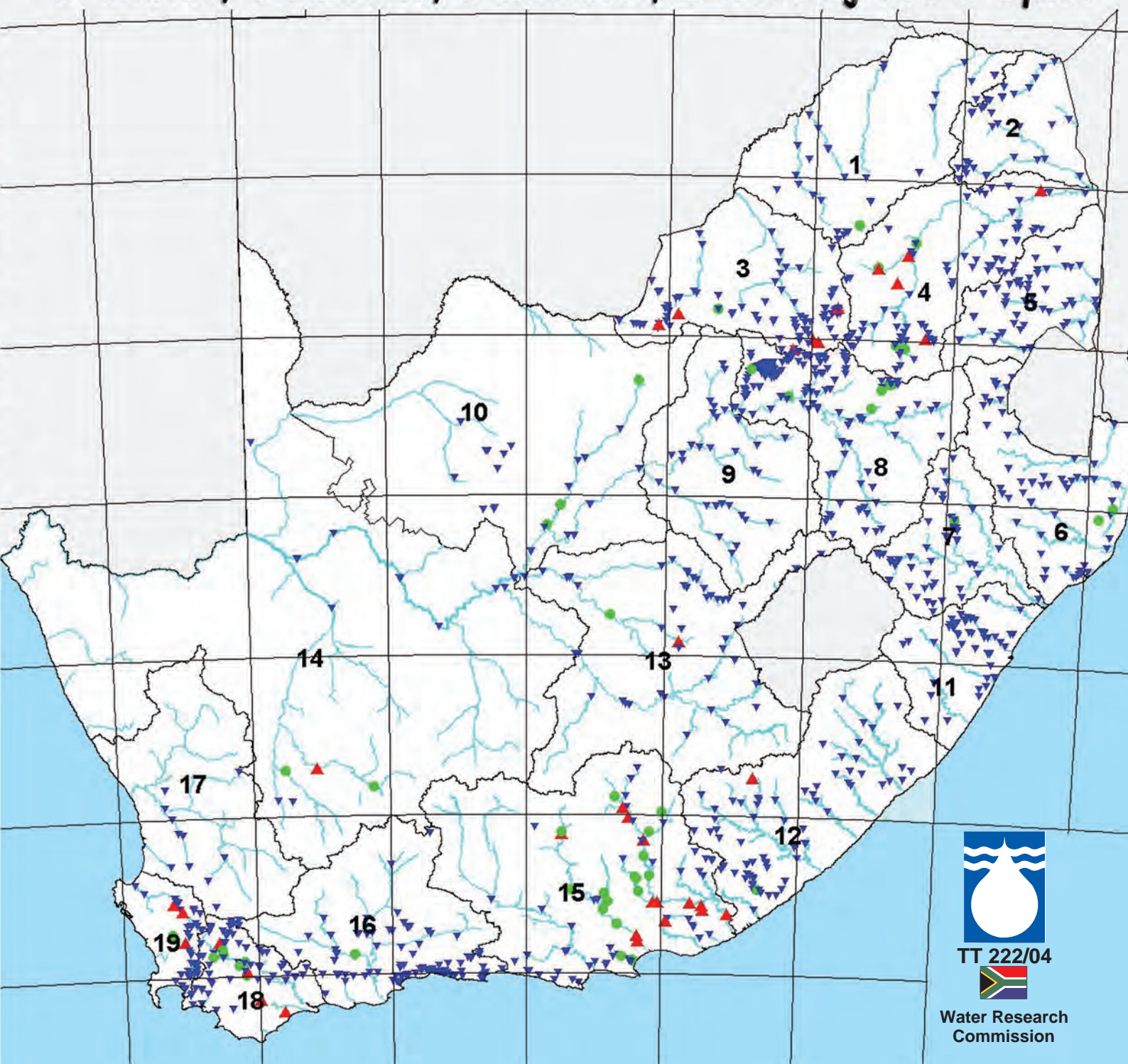


Feasibility of Water Fluoridation for South Africa

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TT 222/04



Water Research
Commission

FEASIBILITY OF WATER FLUORIDATION FOR SOUTH AFRICA

Report to the Water Research Commission

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WRC TT 222/04

FEBRUARY 2004

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The publication of this report emanates from a project entitled:
*Feasibility of using water as the vehicle for the distribution of fluoride to the
South African population*
(Consultancies No's K8/498, K8/499, K8/500, K8/501 and K8/502)

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ISBN 1-77005-108-2

Printed in the Republic of South Africa

EXECUTIVE SUMMARY

Background

On September 8, 2000, the *Water Fluoridation Regulations* were published in the Government Gazette. Water fluoridation thereby became mandatory after six years of intense debate since the National Health Plan first proposed water fluoridation as a primary health care measure in 1994. Practically, this meant that all water providers had to register for compulsory water fluoridation by September 2001 and commence with fluoridation by September 2003, unless exempted by the Department of Health on the basis of specifically listed reasons. The implementation of the process, however, did not proceed as planned. Most water providers applied for exemption, based on a variety of reasons. During the same time, new municipal legislation was promulgated which raised some uncertainties about the role of municipalities (where they are bulk buyers of water from water boards) in the registration process. Moreover, some major water providers took a public stand against water fluoridation. These factors led to a partial impasse. In order to resolve these issues, a Joint Fluoridation Implementation Committee (JFIC) was formed towards the end of 2002 with representation from all the major stakeholders. At the same time, the Water Research Commission (WRC) offered to fund this desk-top study to systematically catalogue and consider the many concerns raised, within a specific South African context. To get the broadest coverage, the WRC assigned the project to five team members from different specialist areas. Each member had to consider the fears, the claims, the counter-claims and unknowns about water fluoridation from his/her professional perspective. Some may be irrelevant or not as serious as claimed, and can therefore be dropped from further consideration. However, where problems do turn out to be potentially serious or where not enough is known to draw a reasonable conclusion, these problems should be flagged for special consideration by the water providers – those who are ultimately responsible for the safe and responsible implementation of water fluoridation. Remaining problems should be pursued in the national interest. The overriding objective was not to re-open the debate *whether* South Africa should fluoridate or not, but to *assist* water utilities and decision makers at all levels in considering the practical and potential problems associated with water fluoridation.

Medical and Dental Issues

The complex relationships between human health and fluoride are addressed first, as this is the area most emotionally and vehemently debated. The arguments around health had been mostly discounted during the political debates prior to the approval of the legislation, but the main points bear repetition as it is essential to incorporate them in a public communication strategy. There is no debate about the fact that fluoride has beneficial dental effects at low intake concentrations, as well as harmful dental and other health effects at higher intake concentrations. (Any viewpoint that takes a simple “all benefit” or “all harm” stance is either ill-informed or ill-intentioned.) The uncertainties revolve around the *threshold* concentration at which the effects turn from beneficial to harmful, and the *nature* of the harmful effects. These questions probe a highly complex issue on which there is very little scientific certainty or even agreement. This report considered both human health data (often the road taken by the pro-fluoridation lobby to show that there is no harm) as well as animal and *in vitro* data (often the road taken by the anti-fluoridation lobby to point to all the conceivable problems which may be encountered). Both data types have severe limitations - human epidemiological studies are insensitive to small but real effects, whereas animal and *in vitro* studies have obvious problems in extrapolating their results directly to humans. They should not be used in opposition, but as complementary tools to probe a complex issue such as water fluoridation. Formal health risk methodology was used as a logical, intuitive framework for weighing and comparison of the data from different studies. A final concern was that South Africa consists of a population with large gradients in

income, nutrition levels and immuno-compromise. Some population groups are probably more sensitive to fluoride than others; an aspect requiring serious consideration by policy-makers. The specific findings of this chapter are:

- The evidence for toxic effects is well established. For dental and skeletal fluorosis reasonably firm thresholds had been established, but the evidence is not available to be able to establish the threshold for other potential toxic effects. The evidence for carcinogenic effects, however, is inconclusive. The United Kingdom's Medical Research Council Working Group, for example, concluded that there is no firm evidence linking water fluoridation to cancer, but the group recommended an updated analysis of the data on fluoridation and cancer rates be carried out.
- The York Review (widely recognised as being one of the better reviews carried out on the subject of water fluoridation) indicated that water fluoridation results in an average improvement of 14.6% of caries-free children, with a median improvement of 2.25 caries free teeth. Some local studies (unfortunately not considered to be rigorous enough for inclusion in the York Report) indicated better results where fluoride intake was increased.
- The total dietary intake of fluoride is more than just that from water. There are other ingestion routes such as food, dust, air and toothpaste. Very little is known about true total exposure to fluoride, either here or in the rest of the world. An indication of total exposure to fluoride of South Africans is therefore needed.
- A health risk assessment, assuming water fluoridated at the maximum level of 0.7 mg/l as the only entry route, indicated a hazard index of 0.4, which is lower than the theoretical threshold of 1.0. (Hazard indices below 1.0 indicate an acceptable health risk.) When estimates of the other entry routes are added to that of water, the hazard index jumps to 2.0. In this case, the non-water routes account for a hazard index of 1.5 on their own. It should be noted that these estimates are not absolute and associated with a wide range of uncertainty. It nevertheless supports the WHO view that the margin between harmful and beneficial effects is narrow. The Department of Health therefore has to develop a careful, transparent procedure to set the optimum water fluoridation level for each individual water provider.
- South Africa has a very large potentially sensitive sub-population, affected by malnutrition and HIV/AIDS, that may experience some detrimental effects of fluoride at the proposed water fluoridation concentration. There are many unknown factors with regards to the toxicity and carcinogenicity potential of fluoride and this may be exaggerated in the immuno-compromised. An assessment of the sensitivity to the toxic effects of fluoride of this sub-population therefore needs to be made, as this could have serious implications on water fluoridation and general health policy.

Environmental Issues

The impact of water fluoridation on the environment (which receives the return flows) presented in this report sheds new light on an aspect not quantified locally before. The methodology described as well as the preliminary findings will be of valuable assistance to water providers and regulatory agencies as they have to address this concern for each individual case. Initial estimates for eight areas are presented using a mass balance approach in conjunction with average annual flow rates and median fluoride concentrations. After allowing for fluoridation to the maximum mandated level of 0.7 mg/l and adjudicating the effects against threshold concentrations based on existing South African water quality guidelines (allowing for a margin of error), the preliminary findings are:

- Problematic fluoride concentrations were found in five of the eight catchments studied, namely the Vaal River between the Barrage and the confluence with the Orange River, the Upper Crocodile and Pienaars River systems, the Sand River downstream of Virginia and Welkom, the Modder River

upstream of the Krugersdrif Dam to the confluence with the Riet River, and at several points in the Waterval River system. Four of these potential problem areas would result from fluoridation of the Rand Water supply. This points to the Rand Water supply area as being the most critical area requiring further investigation.

- The results of the preliminary analysis did not indicate undue problems in the Msunduzi, Berg and Buffalo Rivers.
- Other potential problem areas need to be identified and, where warranted, investigated.

These findings were based on a simplified methodology in order to obtain a first-order estimate of potential problem areas. For a detailed investigation into a specific catchment area, the methodology can, and should be, refined to address at least the following:

- It is essential to investigate the effect of hydrological variation. Unusually wet conditions over the last few years could also have distorted the results. A less biased analysis based on a longer hydrological sequence is required to give a more balanced view of the likely impact.
- Evaporative concentration of fluoride should be addressed, which occurs during storage in major dams and also when steam is raised or water is used in cooling cycles. This would tend to increase the estimated fluoride concentrations.

The most important recommendations, following from the desk-top study presented, are:

- Detailed assessments are required in the following priority areas - Vaal Barrage and downstream Vaal River system, Crocodile River, Waterval River, Modder River and Sand River.
- Further research should be aimed at determining which other areas warrant more detailed investigation. This should include the Molopo and Cowie River systems and other areas identified after discussions with all water boards and major water suppliers.
- System modelling is required to properly assess hydrological variation and to account for both present and projected future conditions.
- Water use within major supply areas should be examined and effluent fluoride data collected to determine the extent to which fluoridated water would be concentrated before discharge as effluent.
- The time frame for implementation of fluoridation in certain sensitive areas should be revised to allow more time for the essential preparatory research to be completed.

Technical Issues

There are numerous practical matters to be considered by water suppliers before water fluoridation can be implemented. This aspect, unlike the other issues dealt with in this report, is fortunately dealt with extensively in the promulgated regulations. The focus of this section was therefore to critically examine the technical specifications contained in the legislation and to simply focus on those aspects that are not adequately covered. Most of the practical aspects are adequately covered. There are, however, some uncertainties or potential problem areas which need to be resolved:

- The allowable tolerances for fluoridation dosing accuracy are strict and continued compliance will require special care and diligence. The major obstacle here appears to be the degree of accuracy of fluoride measurement in water, a conclusion also borne out by inter-laboratory comparisons as well as operating experience from others who have been practising fluoridation for many years. A benchmarking and networking system amongst water providers should be established to improve the measuring accuracy of fluoride to ensure compliance to the strict dosage control ranges called for.

- A potential problem of fluoride precipitation exists when fluoride is added in a high pH regime, or when fluoride is added at low pH in the presence of aluminium (possible in low-alkalinity water such as in the southern Cape). It is suggested that typical water quality profiles are assembled at those South African water providers where these concerns are raised and systematically model the chemical speciation upon fluoride addition with a program such as MINTEQ. This will demonstrate to what extent the concerns about aluminium and other complexes with fluoride are warranted, and what could be done about them.
- No standard formats and electronic documentation requirements for the detailed reporting system are specified, which may make further reporting or analysis unnecessarily tedious. Similarly, the incident management and reporting procedures are sparsely detailed and may require further amplification. A uniform and preferably electronic reporting system for automated submission and rapid review of water fluoridation records should be developed.
- In the legislation and guidelines, much emphasis is placed on having a detailed, formal, written programme which will be the blueprint for all employees at all levels for dealing with normal operation, maintenance and disaster management – without giving any guidance on what is required. The development of such a comprehensive plan by each water provider is a costly exercise. There is a need for a generic blueprint programme, which can be amplified and adapted, to the specific needs of each water provider. It is recommended that a generic water fluoridation programme is developed to the satisfaction of the Departments of Health and Water Affairs, which can then be used as a standard template by the different water providers to detail their own programmes in a cost-efficient, time-efficient and uniform way.
- The general Class III operator qualifications required are high and, depending on how the regulation is interpreted, may be a limiting factor to prevent widespread implementation of water fluoridation in South Africa.
- There is a definite and urgent need for fluoridation-specific training and certification for operators, prior to the full-scale implementation of fluoridation in South Africa. A comprehensive training and certification programme for operators, designers and managers of water fluoridation systems should be designed and implemented.

Economic Issues

The fundamental premise driving the South African water fluoridation legislation is that it can avert dental caries. In the absence of water fluoridation, dental caries have to be addressed by filling or other dental care. An economic cost-benefit analysis was conducted to assess whether, and under which conditions, water fluoridation is the better economic option. A number of assumptions had to be made for this analysis:

- The cost of water fluoridation was based on South African costs estimates. This ranges from about 2.0 to 2.5 c/kl for treatment plants with a capacity of 10 Ml/d or more, with a fairly steep increase in costs below this capacity.
- The cost of an average filling was estimated to be R158.95, based on South African dental rate scales.
- Water fluoridation was estimated to avert one filling every five years, equivalent to a reduction rate in dental caries of 20%. This is a conservative assumption, as some local evidence suggests that it may be higher in some areas.
- For negative health effects, environmental impacts and defluoridation needs, zero costs were assumed. The basis for this assumption was not information that these costs are indeed zero, but insufficient generally accepted information on their scale.
- The cost-benefit analysis was carried out for two population sizes, namely populations of 100 000 and 5 000 respectively:

For the population of 100 000, the economic benefits outstripped the costs by a factor of 4.4 times, thus indicating that water fluoridation is a cost-effective means of dental caries reduction. The economic rate of return of water fluoridation, in more formal terms, is 29% which is significantly more than the required minimum of 10%. For small populations of less than 5 000 people and small plants (fluoridating less than 2 Ml/d) the operational and capital costs per capita increase substantially. Under these circumstances the benefit-cost ratio drops to 0.73 (less than 1) and the internal rate of return to 5% (less than 10%). The conclusion is that water fluoridation is economically unfavourable for small populations of less than 5 000. Water fluoridation will therefore be cost-efficient in large metropolitan areas in South Africa if the intended dosage indeed has no negative health and environmental impacts, but not so in very small communities. It is deduced that at some intermediate population size the project becomes cost-efficient. A more comprehensive cost-benefit analysis should be undertaken to determine this threshold.

There is little doubt that the main limitation of the economic study is the lack of information on the negative health costs at fluoridation concentrations between 0.5 and 1.0 mg/l. This lack of information creates much uncertainty and will cause cost-benefit analyses to yield inconsistent results. There is much empirical international evidence for assuming that it is safe to fluoridate water between 0.5 and 1.0 mg/l. In this case there are no negative health costs to worry about. However, some uncertainty remains about the other fluoride ingestion routes as pointed out in other parts of this report, which will continue to cast a shadow on the economic analysis unless better resolved and quantified.

Social and Legal Issues

As a final step, a wide range of social and legal issues were addressed. These are all arguments that have been raised in the national debate at some point or another. After analysis, the following main conclusions were reached:

- The Fluoride Regulations were lawfully made, in full accordance with the way in which powers and functions have been allocated between the three spheres of government under the Constitution. While municipal Water Service Authorities are responsible for ensuring that water supply systems function properly, whether operated by themselves or by a Water Provider, any decisions regarding national and minimum water quality standards are legally the function of the Ministers of Health and Water Affairs, and not of the individual municipal councils or Water Authority. The outcome of any constitutional challenges will therefore depend on the strength of expert evidence, and the persuasiveness of the argument put forward by opponents to fluoridation.
- Legal liability will depend on the nature of the claim. Claims for the improper implementation of the regulations will be against the relevant Water Service Authority, while claims against fluoridation itself will be against the Minister of Health.
- Defluoridation of water supplies where natural levels exceed the recommended level of 0.7 mg/l is not required by the regulations. The responsibility of water service providers regarding natural fluoride levels above the recommended level needs to be clarified. It is meanwhile recommended that the issue of defluoridation be investigated further, especially with regard to any possible obligation on Water Service Providers to reduce excessive fluoride levels, which could have significant financial implications for the municipalities concerned.
- Although the regulations are aimed at reducing the incidence of dental caries, particularly in poorer communities, many rural communities will in all likelihood never benefit from water fluoridation, due to technical constraints both in the short and the long term. For those sections of the population who will not receive fluoridated water, it is recommended that the Department of Health continues to

investigate the possibility of using other forms of fluoride in conjunction with education campaigns, in order to improve oral health amongst *all* South Africans.

- There are fears that the cost of introducing water fluoridation will delay efforts to connect poor communities to piped water. However, DWAF has clearly stated in a presentation to the National Portfolio Committee that the provision of Free Basic Water remains the priority.
- Greater clarity is required on the matter of public comment and the process to be followed by municipalities when receiving these comments. How will these comments be taken into account?

Closure

If nothing else, this study demonstrates that the water fluoridation legislation has sparked, and indeed deserves, a multi-faceted debate covering a broad range of expert areas and viewpoints. Water fluoridation has both beneficial and harmful effects, some of which are direct and obvious, with other secondary effects which are not so obvious. In a country as diverse as South Africa, it is obvious that one size cannot fit all. The South African legislation consequently calls for each water provider to individually register for water fluoridation, reflecting the unique requirements and constraints of each. It further requires individual consideration of each application, leading to either exemption, postponement or the setting of a fluoridation target for that particular supplier, which will then be followed by close monitoring on local, provincial and national levels.

This report will help water suppliers to identify their own constraints and problems, if any. Where environmental concerns may be a limiting factor, this report provides guidelines for initial assessment and recommendations for more detailed studies. Where costs or manpower requirements may be a perceived problem, this report provides preliminary cost estimates and the additional operational complexity of water fluoridation. If there is some uncertainty on the legal position following new municipal legislation, it is explained and some preliminary interpretations are provided. When non-expert decision-makers at local level may be confused by what appears to be conflicting health views, this report explains the relatively narrow band between beneficial and harmful effects, and in which areas inevitable uncertainties remain.

Water fluoridation is not a useless or even counter-productive dental caries preventative measure, as evidenced by a half a century of international experience by others. Similarly, it certainly is not a trivial or risk-free undertaking, just because it had been previously done by so many others. Its responsible implementation in South Africa, with its unique problems and conditions, will require hard work and the elucidation of a number of areas of uncertainty, enumerated in this report. It is trusted that the report will assist water providers as they continue to grapple with the practical aspects of implementing water fluoridation.

ACKNOWLEDGMENTS

This project was only possible with the co-operation of many individuals and institutions. The authors therefore wish to record their sincere thanks to the following:

The National Fluoridation Committee

Department of Water Affairs and Forestry, Directorate of Hydrology, in particular, Ms M Erasmus, Ms F Sibanyoni and Mr E Holmans who made available key water quality and hydrological data.

The following persons contributed as co-authors to individual chapters:

Dr MJ van Veelen	BKS Consulting Engineers	(Chapter Three)
Dr AD Ceronio	Consultant	(Chapter Four)
Ms K Reynolds	Mallinicks	(Chapter Six)

The following individuals provided valuable insights, documents and data:

Prof A Görgens	Ninham Shand
Mr G McConkey	Department of Water Affairs and Forestry
Mr E Lusignea	Department of Water Affairs and Forestry
Ms A Ramjatan	Umgeni Water
Prof M Seaman	University of the Freestate
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CHAPTER ONE

INTRODUCTION

Johannes Haarhoff, RAU Water Research Group

1.1 Background

The current South African water fluoridation legislation is the result of an initiative taken at the National Medical and Dental Association Conference in 1990. This led to a symposium on water fluoridation held in 1991 under the auspices of the Medical Research Council, where a working group was formed to promote the issue of water fluoridation. As a result, the National Health Plan of 1994 proposed the implementation of water fluoridation as a primary health care measure. The implementation of water fluoridation was then entrusted to the National Department of Health, or more specifically, the National Fluoridation Committee (NFC) operating as a subcommittee of the Oral Health Committee (Moola, 1996). After approximately six more years of consultation and debate, the Water Fluoridation Regulations were finally promulgated during September 2000.

In terms of the Regulations, water providers had to register for fluoridation or to apply for exemption before September 2001. Most water providers applied for exemption, based on a variety of reasons. Moreover, some major water providers took a public stand against water fluoridation, which led to a partial impasse. In order to resolve these issues, a Joint Fluoridation Implementation Committee (JFIC) was formed towards the end of 2002 with representation from all the major stakeholders. At the same time, the Water Research Commission (WRC) offered to fund a project which would systematically catalogue and consider the many concerns raised, taking South African conditions into account. It would flag those areas, if any, that needed special consideration or required more research.

At the time of publication of this report, JFIC has reported some progress towards implementing water fluoridation by selecting a few “front-runners” – plants where fluoridation will be implemented first. It is trusted that this report will make a positive contribution to the NFC, the JFIC and water providers by quantifying and identifying the problems remaining in the way of water fluoridation.

1.2 Objectives

Fluoride has received extensive research and study. As far back as 1992, it was estimated that more than 3700 studies on fluoride and fluoridation had been conducted by governmental and research organizations (Hamilton, 1992). The aim of this project was therefore not to comprehensively review the voluminous international literature on this topic, but to focus specifically on the legislation and intent that will drive water fluoridation in South Africa and to take local conditions into account where they may be different or unique.

To get the broadest coverage, the WRC assigned the project to five team members from different specialist areas. Each member had to consider the fears, the claims and counter-claims, and unknowns about water fluoridation from his/her professional perspective. Some of these may be irrelevant or not as serious as claimed, and can therefore be dropped from further consideration. However, where problems do turn out to be potentially serious or where not enough is known to draw a reasonable conclusion, these problems should be flagged for special consideration by the water providers – those who are ultimately responsible for

the safe and responsible implementation of water fluoridation. Remaining problems should be pursued in the national interest.

It bears repetition to state that the overriding objective was not to debate *whether* South Africa should fluoridate or not, but to *assist* water utilities and decisionmakers at all levels in considering the practical and potential problems associated with water fluoridation.

1.3 Team Members

The Water Research Commission used a fast-track approach to ensure the delivery of this report prior to the first implementation of water fluoridation in terms of the Act. To this end, the following team was constituted in December 2002 to cover the following:

Research manager	Dr Gerhard Offringa (Water Research Commission)
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1.4 References

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Moola, M.H. (1996) Fluoridation in South Africa. *Community Dental Health*, **13** (2)

CHAPTER TWO

MEDICAL AND DENTAL ISSUES

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2.1 Introduction

The reports on the benefits and disadvantages of water fluoridation are numerous with tens of thousands of references in the literature. This study comprised a desktop review, with emphasis to be placed on assessing the potential health effects in the South African context.

The objective of this investigation was to assess the positive and negative health effects associated with fluoridation of water, with the emphasis on assessing the risks and potential risks involved. Specific issues to be addressed included assessing how people are generally exposed to fluoride. This includes total exposure of humans to fluoride, the possible pathways they are exposed through, as well as considering the total dietary intake of fluoride. Some considerations include:

- What proportion of the population will get fluoride via water fluoridation?
- Special considerations will include whether water fluoridation improves the dental health of the most vulnerable and
- How water fluoridation impacts on HIV positive or Aids suffers?

The more recent and internationally accepted references and reviews were used in this study. For instance, the “York Review” (McDonagh *et al*, 2000) commissioned by the Chief Medical Officer in the United Kingdom is one of the more recent and comprehensive of the reviews on water fluoridation, is considered and quoted throughout this report.

It is well known and accepted that fluoride has a beneficial effect of preventing dental caries. It is also known that fluoride is a potent toxicant at high doses. However the range at which detrimental effects are observed and the type of detrimental effect observed appear to be far more controversial. This controversial aspect is investigated in more detail in this chapter.

2.2 Approach

Because of the abundance of reports on the health effects of fluoride and water fluoridation, often with contradictory information, as well as the controversial nature of the subject, an approach that could assess the health issues in an unbiased way had to be used.

Over the last 2 – 3 decades, risk assessment was developed and used as an engineering discipline by various international organisations such as the United States Environmental Protection Agency (US-EPA), United States National Research Council, US National Academy of Science (NAS), and the World Health Organisation (WHO). The approach is embraced as an objective tool for environmental decision-making. It provides a useful paradigm for organising risk science information from many different sources. One virtue of the system is clarity as it makes the risk assessment process accessible so that scientists, regulators, journalists and educators can use the same frame of reference for understanding how the scientific principles and data have been used. The risk assessment approach is used by the WHO in setting drinking water quality guidelines. It involves a four-step process that is explained and depicted in a later section. The

risk assessment *per se* is the process examining the probability of an adverse effect, which in turn is used by decision makers. Estimates of risk are necessary for some environmental decisions. However, in most cases risk assessment is only one of the many factors that enter into the environmental decision making process. Typically, other factors include risk equity (ie, who bears the risk), technical feasibility, economic costs and social values, to name a few.

Risk can be defined as the potential to cause harm, or the probability of an adverse effect. Risk assessment is a process that estimates the probability or potential to cause harm, to allow environmental decision makers to base their decisions on the best available data. Even though the assessment process uses the best available scientific data to evaluate the risks of adverse health impacts, human health risk assessment is not an exact science. Several assumptions and uncertainties are involved in predicting whether or not human health will suffer as a result of exposure to hazardous substances. Where data accuracy is low or assumptions have to be made, the approach taken is always a precautionary one so that any errors are on the side of human safety.

Risks cannot be measured directly, but only estimated. Real risk can only be estimated AFTER damage has occurred (as would typically be assessed in an epidemiological study). For risk assessment, chemical hazards and exposures to the hazards are estimated to provide an estimated risk. The accepted risk assessment approach in identifying hazard potential makes use of available data (human, animal and *in vitro* data), which is then ranked according to the quality of the data. Human data is obviously given more weight, but where human data is absent, animal and *in vitro* data is used. It should be noted that using this risk assessment approach, the studies referred to in this report include not only the “York Review”, which exclusively considered human studies, but also animal and *in vitro* studies.

2.3 Beneficial Effects Of Fluoride

The therapeutic effect of fluoride is well documented. Fluoride prevents dental caries. One of the more recent and comprehensive reviews of water fluoridation to date is the “York Review” (McDonagh *et al.*, 2000). This study carried out by the University of York was commissioned by the Chief Medical Officer of the United Kingdom, with the aim to carry out an up-to-date expert scientific review of fluoride and health. This review has been favourably received by much of the scientific community although some criticism has also been expressed. Of more than 3000 references found in the literature by the researchers, a total of 254 water fluoridation studies met the relevance criteria and were included in the review. Nevertheless, the particular objective analysing the effect of water fluoridation on dental caries is a thorough one. A **meta-analysis**¹ was carried out on 26 studies that met the inclusion criteria of the reviewers for the specific objective. The results of the review indicated a median improvement in the percentage of caries-free children of 14.6%. Most (19 of the 26) studies found a statistically significant improvement, one found a significant decrease and the remaining studies did not detect statistically significant changes. These results as presented in the “York Review “ (McDonagh *et al.*, 2000) follow in Figures 2-1a & 2-1b,

Studies have also been carried out in South Africa which demonstrate the differences in the prevalence of dental caries according to fluoride levels in water (du Plessis, *et al.*, 1995; du Plessis, 2000). The results showed, as much as 80% lower caries levels where fluoride levels in the water were 0.54 mg/L. These

¹ **Meta-analysis** is a means of comparing and synthesising studies dealing with similar health effects and risk factors. It is intended to introduce consistency and comprehensiveness into what might be a more subjective review of the literature. Meta-analysis may enhance the understanding of associations between sources and effects that may not be apparent from individual epidemiological studies.

studies were not included in the York Review, as they did not meet the inclusion criteria used. Grobleri *et al.*, (2001) studied dental caries and fluorosis in three areas in South Africa. These areas experienced different fluoride levels in the drinking water. They found a statistically significant association between high fluoride levels and high levels of caries. [This study was published after the “York Review”.]

An additional objective of the “York Review” was to assess whether water fluoridation resulted in a reduction of caries across social groups and between geographical locations bringing equity. The finding was that there was little evidence that water fluoridation reduced social inequalities (McDonagh *et al.*, 2000). It is not obvious from the review whether this finding can be extrapolated to developing countries where many people do not have access to either toothbrush or fluoride toothpaste.

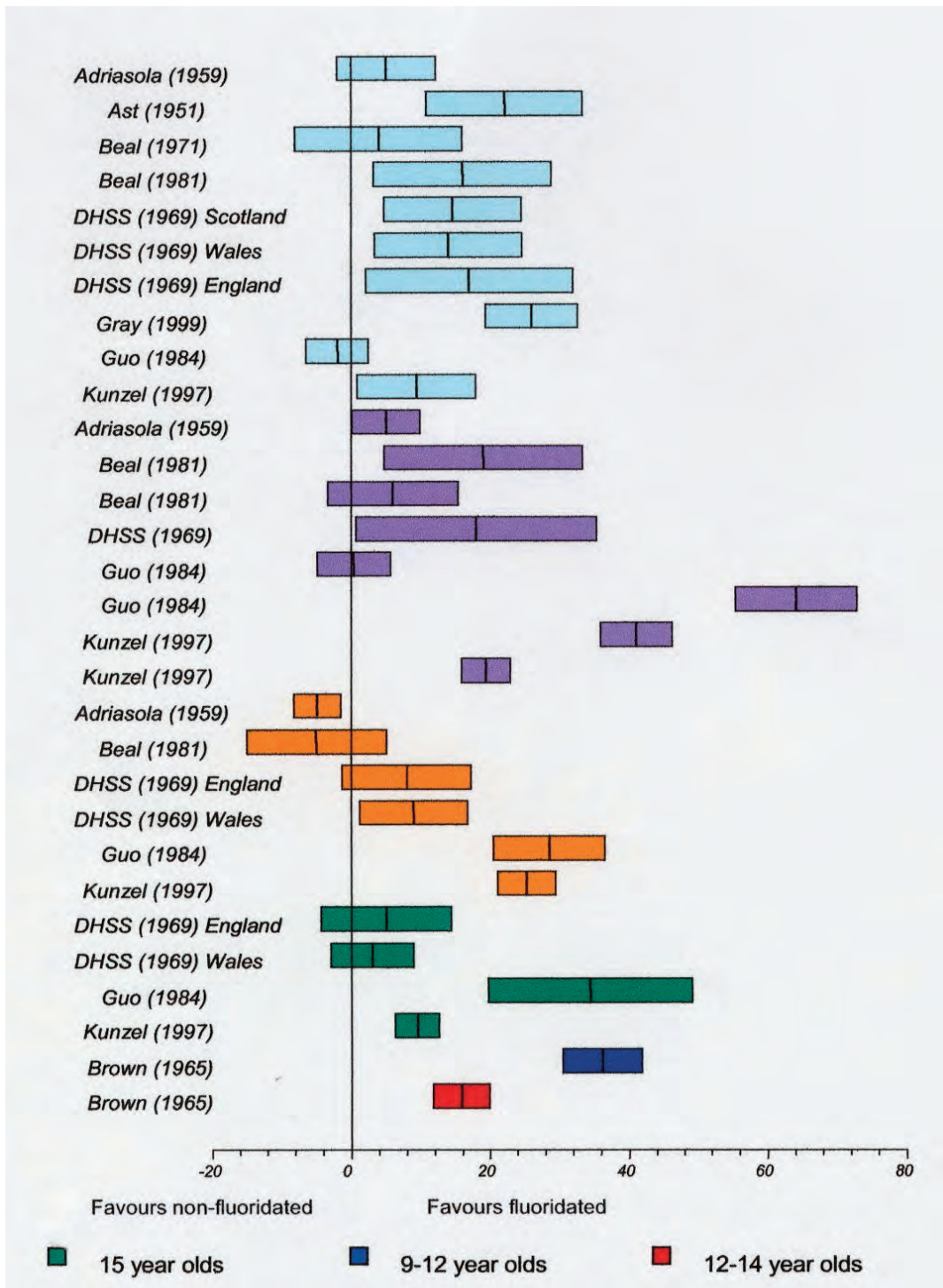


Figure 2-1a From "York Review": Increase in % caries-free children in fluoridated compared to non-fluoridated areas (Source: McDonagh et al., 2000)

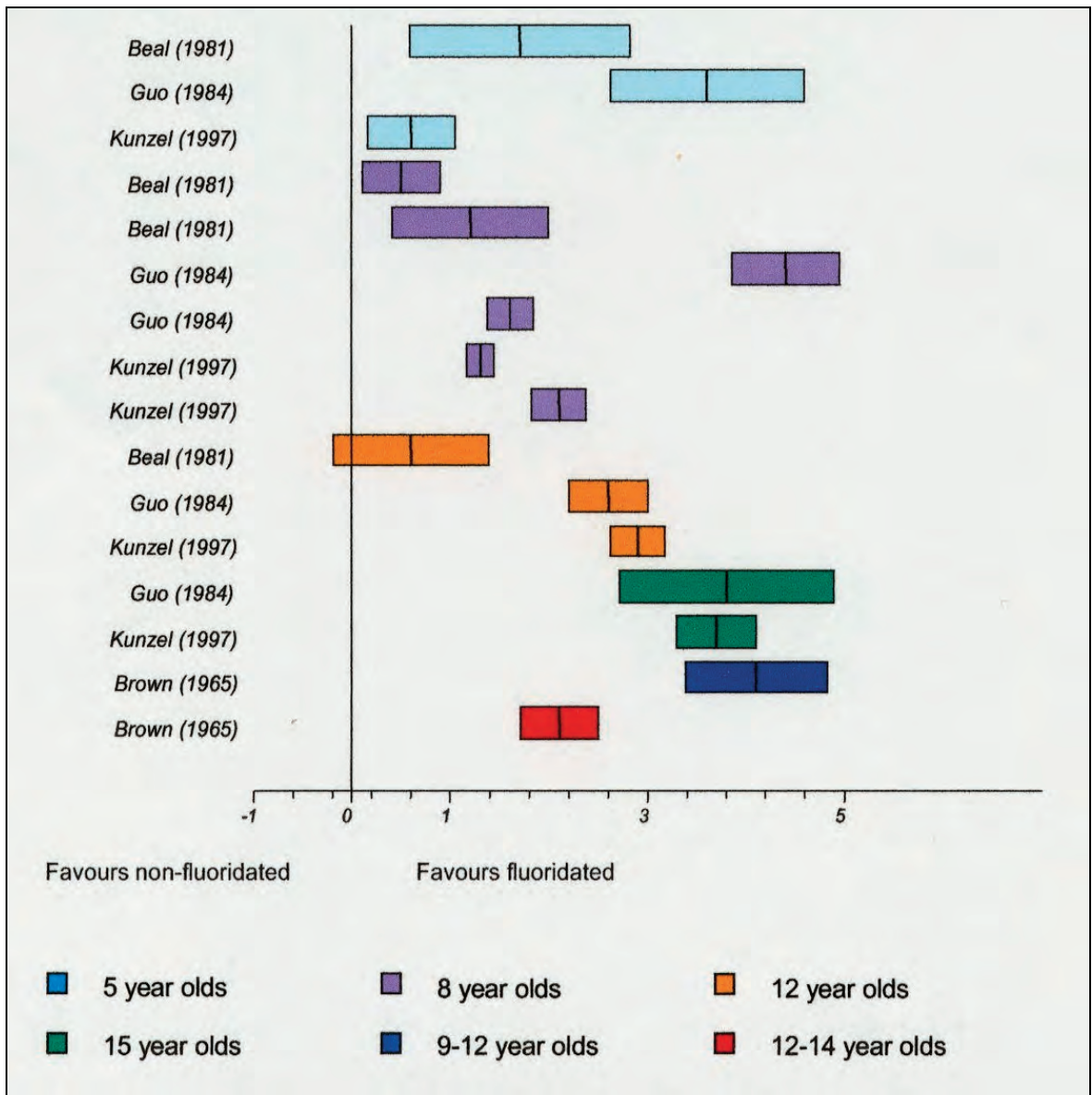


Figure 2-1b. From "York Review": Improvements in number of teeth due to fluoridation- Change in number teeth not decayed, missing or filled (changes in dmft/DMFT score) (Source: McDonagh et al., 2000).

The following figure (Figure 2-2) as presented by Bailey (2002) serves to provide an illustration of part of the debate of the benefit of water fluoridation. Dental caries levels are shown to reduce as much in countries where no water fluoridation is taking place as where it has. This decrease in dental decay has been attributed to improved dental hygiene, with the introduction of fluoridated toothpastes and not as a result of water fluoridation (Sheiham, 1994).

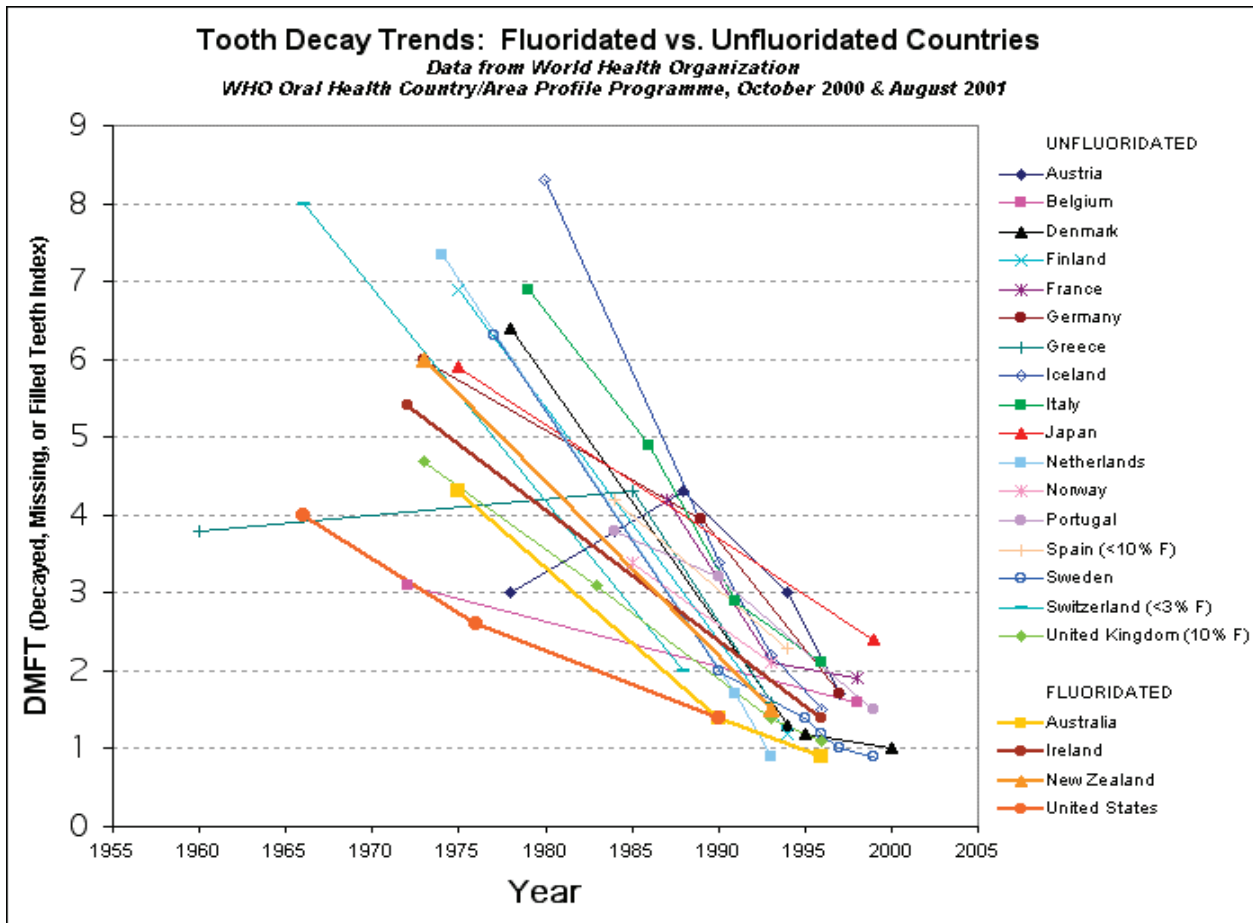


Figure 2-2. Tooth decay trends over time in countries practicing water fluoridation versus those not practicing water fluoridation (source Bailey, 2002)

South Africa was not included in the figure above. However, according to World Health Organisation (WHO) records, South African data for the DMFT (decayed, missing or filled teeth) index from 1988-9 is reported as 1.7 for 12 year olds and 3.3 for 15 year olds. More recent, although selected data, reflects the DMFT scores for 12 year olds to range between 0 and 1.22 - 1.43 (Brindle *et al*, 2000, du Plessis, 2000, Hartshorne *et al*, 1994). This is within the range that is illustrated in the figure above. More information comparing DMFT scores and sugar consumptions for African countries from the WHO database is available in the appendix. There is some dispute as to whether the beneficial effect is as great as many claim and if it is as a result of systemic or topical application. In the United States' CDC (Centers for Disease Control and Prevention) report "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States" (2001) the beneficial effect is stated as follows:

"The laboratory and epidemiologic research that has led to the better understanding of how fluoride prevents dental caries indicates that fluoride's predominant effect is post-eruptive and topical and that the effect depends on fluoride being in the right amount in the right place at the right time. Fluoride works primarily after teeth have erupted, especially when small amounts are maintained

constantly in the mouth, specifically in dental plaque and saliva. Thus, adults also benefit from fluoride, rather than only children, as was previously assumed.

2.4 Methodology: Health Risk Assessment Approach

Health risk assessment is the process of determining if an activity may impact on humans. It involves a quantitative or qualitative process to characterise the nature and magnitude of risks to public health from exposure to hazardous substances released from specific sites. Risk is a combination of two factors, namely: the probability that an adverse effect will occur; and the consequence of that event.

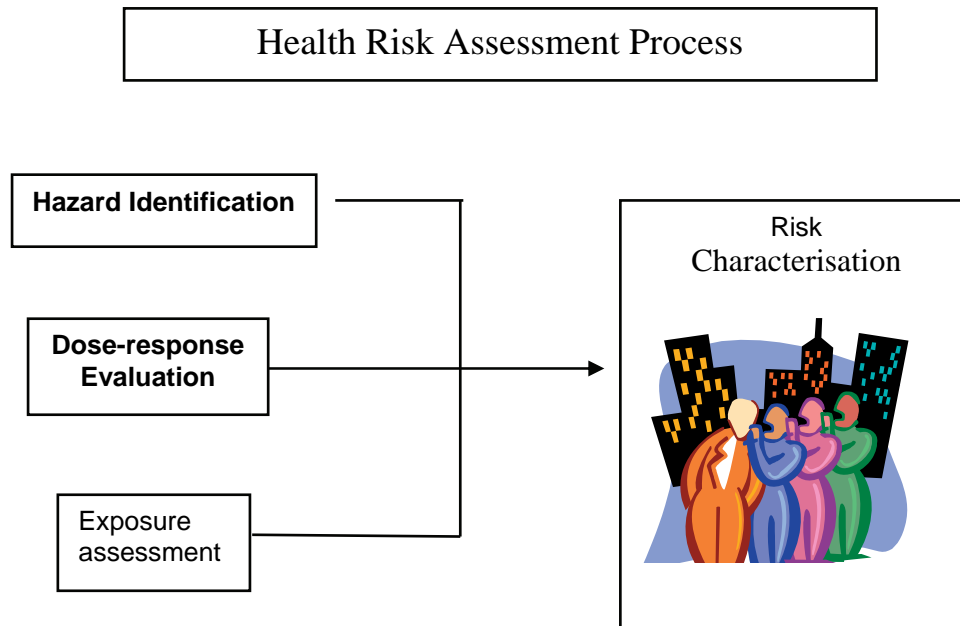


Figure 2-3. The Health Risk Assessment Process

2.4.1 Hazard Identification

Hazard identification establishes whether exposure to an agent can cause harm. It is usually based on primary data from epidemiological studies and animal toxicology studies. Chemical hazards may be either of a carcinogenic or a toxic nature. The methods used to describe these two classes of hazards are different. Once a health hazard has been identified, the remainder of the process involves the description of the hazardous effects.

2.4.2 Dose-response Assessment

This step involves characterising the relationship between the amount of an agent and incidence of an adverse effect in the exposed population.

2.4.2.1 Toxicants

It is general practice to assume that toxic effects have a “threshold level”, where any exposure below that level will be considered to be safe (or even have a therapeutic effect – see Figure 2-4 below). Estimates of toxic hazard are then expressed as measures of the exposure to the chemical that could occur over a

prolonged period without ill effects. Exposures below this reference level are assumed to be safe. A reference dose (RfD) represents an estimate of the exposure that can occur on a daily basis over a prolonged period, with a reasonable expectation that no adverse effect will occur from that exposure.

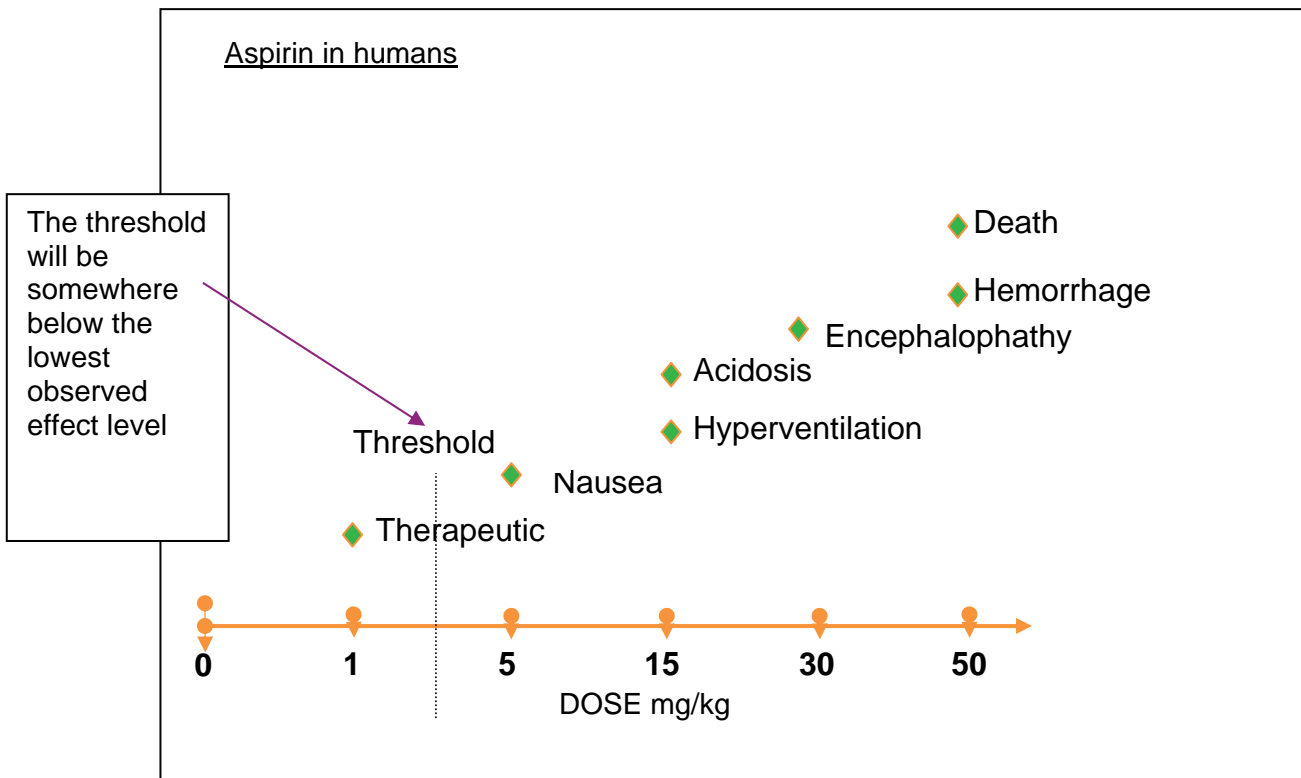


Figure 2-4. Dose-response of aspirin as an example of a toxic chemical dose-response

2.4.2.2 Carcinogens

Chemicals that can cause cancer are generally assumed to have no threshold (this may not be true for some chemicals and cancers). Dose-response assessment for carcinogenic effects is generally based on a linearised multi-stage model of carcinogenesis. The model assumes that at low doses, a straight line can approximate the relationship between exposure and carcinogenesis. Therefore, any non-zero exposure entails a finite risk such that extrapolates through the origin and can be solely described in terms of its slope. This is illustrated in Figure 2-5 below. This slope gives an indication of how potent a chemical is in causing cancer and is known as the slope factor of a carcinogen. Slope factors may be derived from human or animal studies.

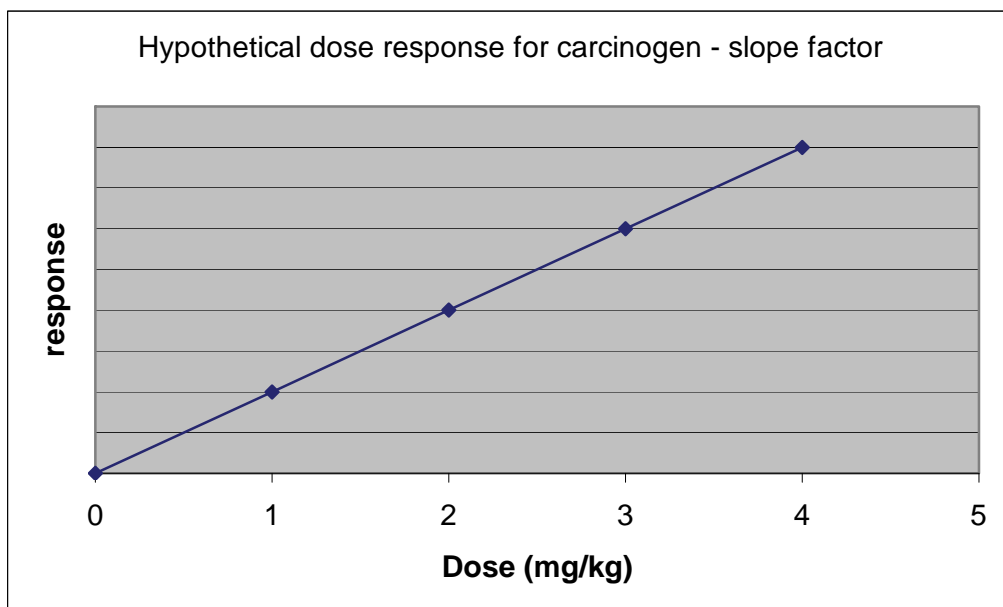


Figure 2-5 Example of carcinogen dose-response

Carcinogens are further classified by the US-EPA according to their weight-of-evidence (Table 2-1 below). A chemical may for instance be classified as a class A carcinogen if there is sufficient human data to indicate its carcinogenicity. Furthermore, if there is insufficient evidence from human, but sufficient evidence from animals, then it may be classified as a B1 or B2 carcinogen, also known as a “probable carcinogen”.

Table 2-1. US-EPA Carcinogen Weight of Evidence Classification System

Human evidence \ Animal evidence	Animal evidence				
	Sufficient	Limited	Inadequate	No data	No evidence
Sufficient	A **	A	A	A	A
Limited	B1	B1	B1	B1	B1
Inadequate	B2	C	D	D	D
No data	B2	C	D	D	E
No evidence	B2	C	D	D	E

** With A = human carcinogen; B1 = probable human carcinogen *limited epidemiological evidence*; B2 = probable human carcinogen inadequate human data but sufficient animal data; C = possible human carcinogen; D = not classified as carcinogen – no data; E = evidence of non-carcinogenicity

2.4.3 Exposure Assessment

Exposure assessment deals with measuring or estimating the intensity, frequency and duration of human contact with the hazardous agent. In other words, assessing how much of the agent one is exposed to, how often and for how long. This step is the calculation of the dose of a particular population. The exposed population may vary with regards to nutritional status, age and extent of exposure. Every exposure assessment should address the possibility of whether the exposed population contains any subgroups that will be particularly sensitive to the toxic effects of the chemical under study.

A typical dose expression would be milligrams of chemical per kilogram of body weight per day. Different dose measures are used in risk calculations for toxicants and carcinogens. For the toxicants an average daily dose (ADD) is calculated and for the carcinogens, a lifetime average daily dose (LADD) is calculated.

2.4.4 Risk Characterisation

The process of risk characterisation combines the information on exposure and dose-response into an overall estimate of risk. Risk characterisation is the final step of the risk assessment, which provides an indication of the health effect under the conditions of exposure described in the exposure assessment and the identified dose-response relationship. All risk estimates involve uncertainty and only reflect the risks associated with the assumptions that have been made.

Quantitative risk estimates are presented as numbers, but mean very different things for toxic risks and cancer risks. Toxic risks are numbers that reflect whether an exposure was larger or smaller than a specified safe level of exposure (the reference dose or RfD). In contrast, estimates of cancer risks are probabilities that express how likely an exposure to a particular chemical will lead to cancer in the exposed population.

2.4.4.1 Risk characterisation for toxic risks

Toxic risks are expressed by a number that is a ratio of doses referred to as a hazard quotient / index. Toxicants are believed to have a threshold value at which no adverse effect will occur over a lifetime exposure to the substance. Any estimate that is greater than one indicates the possibility of a risk. If a toxic risk estimate is presented as 0.001, this means that the estimated exposure is only 1/1000th of that presumed to be safe for a lifetime exposure.

2.4.4.2 Risk characterisation for carcinogenic risk estimates

Risk estimates are typically hypothetical risks of individual risk of developing cancer (but not dying of cancer). In other words, the risk estimate reflects the probability that an individual will get cancer from the specified exposure. The risk estimate is presented as either 1 in a million or 1×10^{-6} or 0.000001. The estimate reflects the risk to an individual and not the number of cancers that would be expected in a population, except in the unlikely event that all members in population have identical exposure. It is also important to remember that the risk estimate is a hypothetical estimate and does not reflect real incidence rates.

2.4.4.3 Uncertainty Analysis

In a risk assessment of any kind, uncertainty is involved in most of the steps. Several assumptions and uncertainties are involved in predicting whether or not human health will suffer as a result of exposure to hazardous substances. Where assumptions are made it is necessary to take the precautionary approach so that one errs on the side of protecting public health.

2.4.4.4 Errors in The Decision-Making Process

In general, health risk assessments are meant to assist the relevant decision makers in weighing up the risks versus the benefits associated with a particular potential adverse affect – in this case water fluoridation. Different types of errors are described when testing hypotheses, typically "type I" and "type II" errors. If we reject a hypothesis when it should be accepted, a type I error has been made. If we accept a hypothesis

when it should be rejected a type II error has been made. An example of the hypothesis is that fluoride is safe. An attempt to decrease one type I error is accompanied in general by an increase in the other type of error. In practice one type of error may be more serious than the other, and so a compromise should be reached in favour of a limitation of the more serious error. This is also known as the 'precautionary principle'. In the context of this study, one would look at the consequences of making a type I error (*ie*, conclude that fluoride is not safe) versus the consequences of making a type II error, namely concluding that fluoride is safe. One would weigh up the consequences of these two types of errors to use in the decision making process.

2.5 Health Risk Assessment of Water Fluoridation

2.5.1 Hazard Identification of Fluoride

The first step in the health risk assessment is to establish whether fluoride is a hazard or not. The literature is in agreement that fluoride prevents dental caries, and that it is toxic. The dispute is around the types of toxic effects that fluoride produces and the concentrations at which these effects occur.

It is agreed that fluoride causes toxic effects. The agreement ends however when it comes to the nature of the toxic effects and the concentration at which the toxic effects occur. A list of possible toxic effects follows:

Toxic effect	Evidence
Death	Conclusive human studies
Dental fluorosis	Conclusive human studies
Skeletal fluorosis (a crippling condition)	Conclusive human studies
Increased frequency of bone fractures	Inconclusive human studies
Osteoporosis	Inconclusive human studies
Hypothyroidism	Inconclusive human studies
Decreased immune function	<i>In vitro</i> , and inconclusive human studies
Decreased fertility and reproductive impairments	Animal studies and inconclusive human studies

Whether fluoride is a carcinogen or not is widely disputed. There is inconclusive evidence in human studies that fluoride is able to cause cancer, whereas there is sufficient evidence in animal studies that fluoride is a carcinogen. The "York Review" focussed on human studies with the conclusion that there was no evidence that water fluoridation caused cancers of any kind (McDonagh *et al.*, 2000). The most recent study analysed in the review was that of Cohn from 1992. The quality of the research included in the review was not of a high standard. The authors acknowledge that the study does not imply a causal connection between fluoridation and osteosarcoma, but goes on to warn that from the public health perspective, the study results support the importance of investigating the possible link between osteosarcoma and overall ingestion of fluoride. In addition, it is recommended that dentists identify whether children reside in fluoridated communities and appropriately advise on fluoride supplementation. More recent research is indicating the possible link to osteosarcomas in males (Connett, 2003) and will require additional investigations to continue.

There is "equivocal" or inconclusive evidence that fluoride causes cancer in young male rats (National Toxicology Programme, 1990, Bucher *et al.*, 1991) and vast numbers of studies supporting the finding that fluoride is able to cause mutagenicity. (Albanese, 1987, Hayashi *et al.*, 1993, Joseph *et al.*, 2000, Khalil, 1995, Lasne *et al.*, 1988, Lazutka *et al.*, 1999, Meng *et al.*, 1997, Ramesh *et al.*, 2001, Scott *et al.*, 1987, Smith, 1988,

Tsutsui *et al*, 1984, Wu and Wu, 1995). (The ability to cause mutagenicity is an indication that a substance has the potential to be carcinogenic).

Epidemiological studies are notoriously insensitive to small risks. To be able to detect differences between exposed and unexposed groups requires a large sample size as well as accurate exposure information and exposure parameters measured over a long duration (not necessarily a long study duration). The sensitivity limit of even the most sensitive analysis in these studies appears to be a 10 to 20% increase. Risk assessment on the other hand is a predictive tool for estimating small numbers of anticipated adverse health effects at low exposure concentrations. The extrapolation from higher dose studies typical of epidemiological studies is needed to be able to predict the low dose effects typical of risk assessments.

2.5.2 Dose Response Assessment of Fluoride

Possibly one of the more important components of this health risk assessment is the dose response assessment where it is established at what concentrations particular effects (both beneficial and negative) are expected. The WHO (2002) states that *there is a narrow range between intake associated with negative and beneficial effects*.

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Selected summarised data from well-recognised and international peer-reviewed sources is presented within the body of this report. More detailed toxic information from these international organisations such as WHO, TERA (Toxicology excellence for risk assessment), ATSDR (Agency for Toxic Substance Disease Registry), and the US-EPA's IRIS (Integrated Risk Information System), is presented in the Appendix.

A number of toxic effects at various concentrations have been recorded. A range of fluoride toxicity information, extracted from sources such as the Hazardous Substances Database (HSDB) is presented in this section, namely:

- The estimated toxic dose of elemental fluoride (not sodium fluoride) is 5 to 10 mg/kg [human evidence].
- Gastrointestinal symptoms have occurred following ingestions of 3 to 5 mg/kg of fluoride [human evidence]. Death has been reported following ingestion of 16 mg/kg of fluoride [human evidence]. Accidental ingestion of sodium fluoride by children usually does not present a serious risk if the amount of fluoride ingested is less than 5 mg/kg. Fluoride toothpaste typically contains a maximum of 1 milligram of fluoride per gram of toothpaste.
- Dental fluorosis on at least 2 teeth in optimally fluoridated (0.7-1.2mg/L) communities is reported to occur in 30-50% of children [human evidence] (Heller *et al*, 1997, McDonagh *et al*, 2000).
- Skeletal fluorosis is reported to occur at concentrations of less than 10mg/L water [human evidence]
- Non-vertebral fractures were found to occur at 34mg/day [human evidence] (for a 65kg person that is equivalent to 0.5mg/kg/d – For the recommended dosing of fluoride in water of 0.7mgF/L, a dose of 0.02mg/kg/d for a 65kg person).
- Immune systems may be affected at low concentrations. Reports have suggested that concentrations as low as 0.1-0.5 mg/L may have adverse effects on the immune system [*in vitro* evidence] (Sutton, 1987 & 1991, Wilkinson, 1983, Gabler *et al* 1986). The effects included inhibition of activation of neutrophils, decrease in migration rate, to a total loss of migration of immune cells, including neutrophils and monocytes.

- Increased rates of infertility were found in women in areas with 3 mg/L or more F in water [human evidence] (Freni, 1994) as well as a decrease in testosterone concentrations in males drinking water from areas where skeletal fluorosis was observed [human evidence](Susheela *et al.*, 1996).

The following table summarises the available “risk values” for fluoride from the different toxicity database agencies and organisations. Risk values are defined as the dose in mg of chemical per kg of body weight per day (expressed as mg/kg-day) that for toxicity is generally considered to be without adverse effects in populations of humans (including sensitive subpopulations) for the duration of exposure specified.

Table 2-2. Summarised toxic risk values for fluoride (Source: TERA (toxicology excellence for risk assessment))

Organization Name	Agency for Toxic Substances Disease registry (ATSDR)	Health Canada	U.S.EPA
Risk Value Name	Chronic Minimal Risk Level (MRL)	Provisional Tolerable Daily Intake (TDI)	Reference Dose (RfD)
Risk Value or concentration (mg/kg/day)	0.05	0.2	0.06
Year set	1993	1993	1987
Data used to calculate risk value (mg/kg/day)	LOAEL * 0.48	0.2	Not applicable
Dose identified in the critical study, <u>adjusted</u> for continuous exposure (mg/kg/day)	Not applicable	Not applicable	NOAEL** 0.06
Uncertainty Factor	10	1	1
Critical Organ or Effect	musculo-skeletal	Skeleton	Teeth
Species	human	Human	human
Study cited in TERA database	Riggs <i>et al.</i> , 1990	Several	Hodge, 1950

**NOAEL = No observed adverse effect level; *LOAEL = Lowest observed adverse effect level. For instance, the value given in the US-EPA column for the reference dose of 0.06 mg/kg/d is based on a study carried out in 1950, which studied children consuming fluoride in their drinking water. Fluoride levels between 0 and 14 mg/L were investigated. Dental fluorosis was the effect studied. Results of the study showed that fluoride levels between 2 and 10 mg/L produced a linear dose-response curve (increasing mottling with increasing dose). Fluoride levels of 0.1-1.0 mg/L produced no such dental mottling or fluorosis. An assumption of 20 kg body weight and 1 L/day water consumption for children was used, since the children studied were 12-14 years old. It was also assumed that a 20 kg child consumes 0.01 mg of fluoride/kg/d in the diet (IRIS, 1989). Thus, a total intake would be approximately 0.06 mg/kg/d (IRIS, 2003).

2.5.2.1 Factors that may influence toxicity

Sensitive Subpopulations

A number of factors in the human system will affect the toxicity of fluoride. For instance, according to the ATSDR (1993) malnutrition affects the response to fluoride with the toxic effect being more severe in the

malnourished. Studies indicated that vitamin C, magnesium and calcium deficiencies played a major role in this.

Other sub-populations may also be more susceptible to toxic effects of fluoride, namely the elderly, and people with cardio vascular and kidney problems.

HIV+ individuals and Aids patients are possibly also more sensitive to fluoride as a result of the immune system function being affected by fluoride (Balabolkin *et al*, 1995, Greenberg, 1980, Jain and Susheela, 1987, Sutton, 1987 & 1991, and Loftenius *et al*, 1999). The research indicates that immune system cells are damaged and the efficacy is reduced in some immune cells. An additional factor to consider is that HIV+ individuals and Aids patients may also suffer from chronic diarrhoea, which in turn may lead to a state of malnutrition, increasing their sensitivity to fluoride.

2.5.3 Exposure Assessment

The exposure assessment of the risk assessment examines a number of factors, namely:

- Who will be exposed to fluoride via water?
- What concentrations people are exposed to?
- How they are exposed to fluoride? and
- How long are they exposed?

Factors that influence exposure includes the concentration of fluoride in the different medium (water, air, food and soil), and the intake rate of water, air, food, and soil. The first part of the question is the easiest to define.

Who will be exposed to fluoride will ultimately be everyone in the country. At the moment, however, it is only those people with access to water supply / formal water services.

According to the data available from the Department of Water Affairs and Forestry (DWAF) on Basic Water Supply provision, 12 million do not have access to 'adequate water'; 11 million of these are rural and 1 million people are urban. Therefore 26 million people have access to 'adequate water'. Of the 26 million people who would receive 'adequate water', 6 million are rural dwellers and 20 million urban dwellers. In the beginning of the implementation phase it is expected that these 20 million will be the first to get fluoridated water.

How much fluoride people are exposed to is dependent on the concentrations in the different media (water, food, air and soil/dust). It is assumed that a concentration of not more than 0.7mg/L F will be present in fluoridated water. One assumes an intake rate of 2L per day for the average adult intake. It is not anticipated that the free basic 6 kL water that is/will be provided to people will influence the amount of water *ingested* and hence the amount of fluoride that would be ingested via ingestion of water.

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Typical dietary intakes of fluoride are available for some countries. For instance, in the US, dietary fluoride intake was assessed to be between 0.8 and 2.7 mg/d. In the Netherlands it has been measured to be as high as 8 mg/d. In addition tooth brushing is known to add to fluoride intake as people may swallow some or all of the toothpaste. Children in particular swallow toothpaste. Intakes of 3.5 mg per brushing episode have been observed. Fluoride levels measured in food, beverages and other substances are presented in the

appendix and provide an indication of the expected concentrations as well as the variations in concentrations found.

How people are exposed needs to take into account that fluoride may also be found in the air as a result of man-made activities such as phosphate fertiliser production, coal burning, or natural activities such as volcanic activities and marine volatilisation. Inhalation of fluoride where high fluoride coal is used indoors or in volcanic areas such as Tanzania, can significantly contribute to total intake rates (WHO, 2002 draft). Air concentrations will vary according to location and no typical concentration and exposure may be calculated for a large area. People may be exposed to fluoride through ingestion (food, water, toothpaste) as well as through the inhalation route.

How long people will be exposed to fluoride is assumed to be a lifetime, as water fluoridation normally results in a long-term exposure. In addition, the other routes of exposure are also long-term exposure routes.

2.5.4 Risk characterisation and uncertainty analysis of water fluoridation

A quantitative risk assessment has a number of constraints, as there is very limited good quality data available on which to base the assessment on. The original reference dose of the US-EPA of 0.06mg/kg/d was based on a 1950 study looking at dental fluorosis as the effect of concern, not taking any other potential adverse effect beside dental and skeletal fluorosis into account, and assuming a limited total dietary intake of 0.01mg/kg/d during a time when other sources of fluoride were much lower.

Fluoride measurements of typical substances are presented in the appendix and range from high fluoride foods and beverages such as fish and tea, to low concentration foods and beverages. According to the WHO (2003) in areas with high fluoride levels in air and water, daily intakes of fluoride may be as high as 30mg for adults (*i.e.*, equivalent to 0.46mg/kg/d for a 65kg person). The US-EPA reference dose also does not take sensitive subpopulations into account.

The ATSDR chronic minimal risk value was based on musculo-skeletal data as the lowest observed adverse effect level and included an uncertainty factor of 10. Not including total exposure information in the majority of studies conducted on potential health effects of water fluoridation has resulted in a serious limitation in being able to quantify potential health risks.

The following section attempts to provide a quantitative risk assessment for toxic effect as a result of exposure to fluoride. Applying the minimum risk level used by the ATSDR of 0.05mg/kg/d assuming that an adult will consume 2L of water daily, is equal to a consumption of 1.4mg F /day from water. An average adult is assumed to weigh 65 kg, and therefore has an **average daily intake of ~0.02 mgF/kg/d**.

The risk or **hazard quotient** for toxic chemicals is calculated as

$$\begin{aligned} & \text{Average daily dose / reference dose} \\ & = 0.02/0.05 \\ & = 0.4 \text{ for the adult specified as a result of exposure to fluoride through water} \end{aligned}$$

Applying the reference dose used by the EPA of 0.06 mg/kg/d and one assumes the same as above, the hazard quotient

$$\begin{aligned} & = 0.02/0.06 \\ & = 0.333 \text{ for the adult specified as a result of exposure to fluoride through water} \end{aligned}$$

This indicates an average daily dose well within the dose considered safe. The limitations of this calculation are that it does not represent a total health risk assessment, but only a result of exposure through drinking water and the limited dietary intake of 0.01mg/kg/d mentioned above. For instance, more realistic dietary intakes for present day diets is excluded, preparation of food using water is excluded, and ingestion of soil, dust or toothpaste and inhalation are also excluded. If one made assumptions of total dietary intake using the concentrations found in the literature (WHO, 2003) the following risk, more reflective of true exposure, could be calculated:

Hypothetically, using World Health Organisation environmental levels and exposure data (WHO, 2003), an average daily intake rate could be calculated as 1.4 mg for water consumption, a dietary intake rate of 2.7 mg/day is not unreasonable and 2.0mg for the inhalation route

$$= 1.4 \text{ mg(water)} + 2.7 \text{ mg(food)} + 2.0 \text{ mg (air)}$$

$$= 6.1 \text{ mg}$$

$$\sim 0.1 \text{ mg/kg/d for a 65 kg person total intake rate}$$

This results in a hazard index of $0.1 / 0.05 = 2$, which would indicate an exposure twice that considered to be safe resulting in potential harmful effects such as dental fluorosis.²

Using the same hypothetical total exposure calculated above, and the dose where the risk of increased fractures would be expected (as reported by ATSDR, Table 2-2) the hazard index is calculated as follows:

$$= 0.1/0.48$$

$$= 0.208, \text{ which is } \sim 20\% \text{ of the dose where the increase risk of fractures would be expected.}$$

The uncertainty within the exposure assessment component is extremely large. Internationally, we have limited, or no, data on total exposure to fluoride in all media and via all pathways. This is a major shortcoming in being able to accurately predict adverse health effects and, therefore, in our ability to protect public health.

A risk calculation for the potential risk of developing cancer could not be carried out, as a slope or potency factor is not available for fluoride as it remains uncertain whether fluoride is a carcinogen. Animal evidence and mutagenicity data points to the likelihood, including uncertain human studies, but research has not been conclusive. Epidemiological studies are typically not capable of identifying small differences in adverse health effects in exposed versus non-exposed populations. The majority, if not all, of epidemiological studies that have been carried out measuring the health effects of water fluoridation have neglected to address the exposure of individuals via pathways other than water.

Immune system toxic effects were measured both in human and *in vitro* studies, with the human evidence being of an inconclusive nature. Sufficient evidence was available however, to include it as a possibility in the sensitive subpopulation analysis presented in the next section.

Within the dose-response step, uncertainty exists regarding whether the recommended therapeutic level overlaps with the toxic levels for sensitive subpopulations (the malnourished, immune-deficient such as HIV+ individuals, the elderly, very young and kidney patients).

2.6 Sensitive subpopulations

² The hazard index is above 1.0 considering only the air and food exposure route in the dose calculation

An assessment of the potential sensitive subpopulation to water fluoridation was made using malnutrition (using poverty as a surrogate), HIV status, together with the population densities in South Africa. The resultant map combining these factors provides an indication of the areas with the greatest potential sensitive subpopulation groups.

The following figures (2-6 and 2-7) present an indication of the potential sensitive subpopulations that will be exposed to fluoride. Malnutrition was identified as a factor that influences the toxicity of fluoride, with malnutrition causing the toxic effects of fluoride to be more severe (ATSDR, 1993). Poverty was used as a surrogate in this assessment of potential sensitive subpopulations, as no nutritional data or more specifically, vitamin C, calcium and magnesium deficiency data, is available for the South African population. The assumption is made that if one does not have an income, the ability to provide a complete and varied diet is limited (and may even be a large underestimation of the malnourished). This will be even more relevant in urban areas where subsistence farming does not occur to a large extent. This is also the population that will potentially be exposed to fluoride via the water supplies. HIV status was included in the assessment of potential sensitive subpopulations as a result of the immune system being identified as an endpoint of potential fluoride toxicity.

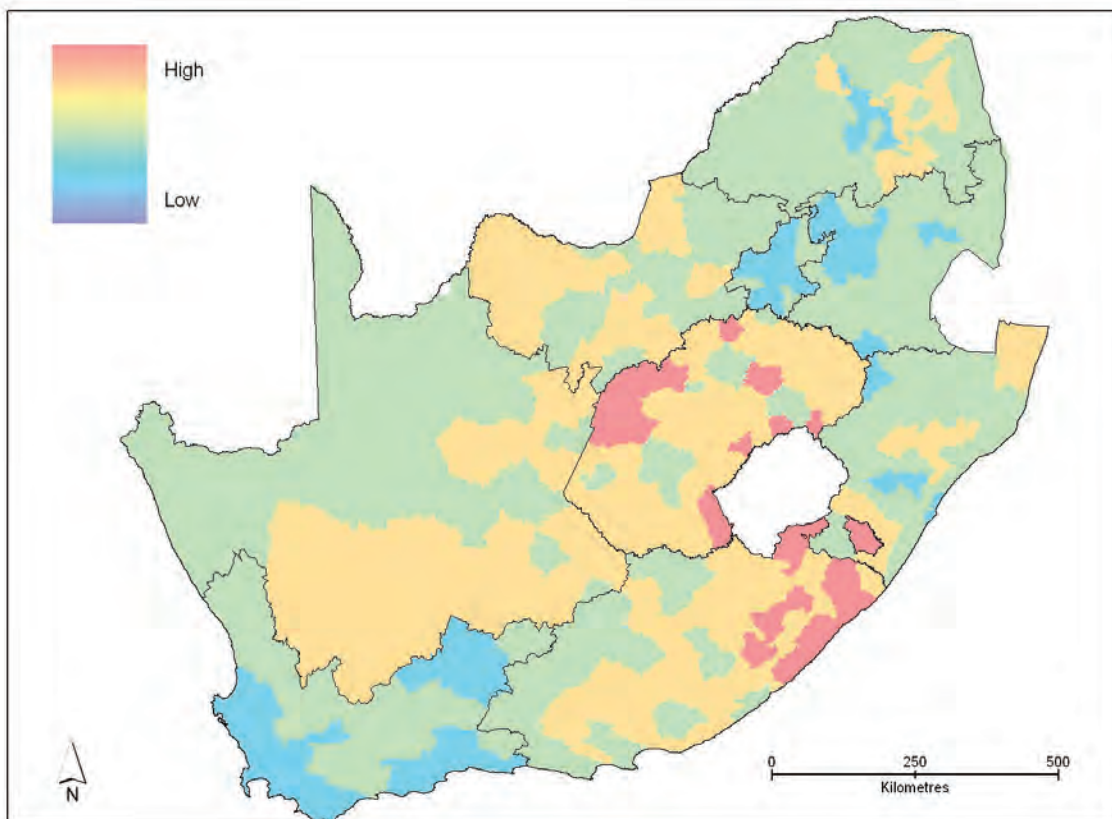


Figure 2-6. Poverty statistics for South Africa, by district (source: Statistics South Africa)

The greatest poverty is seen in the Eastern Cape, Free State, KwaZulu Natal, Northern Cape and Limpopo Province. Areas of greatest poverty reflects 60-80% of the population having a household expenditure of less than or equal to R800 per month.

Areas of HIV prevalence rates are presented in figure 2-7. KwaZulu Natal, Gauteng, Mpumalanga, and Free State are the four provinces with the highest prevalence rates (as high as 37%), followed by North West

Province, Eastern Cape, Limpopo, Province and Northern Cape, with the Western Cape having the lowest HIV+ prevalence estimates (8%).

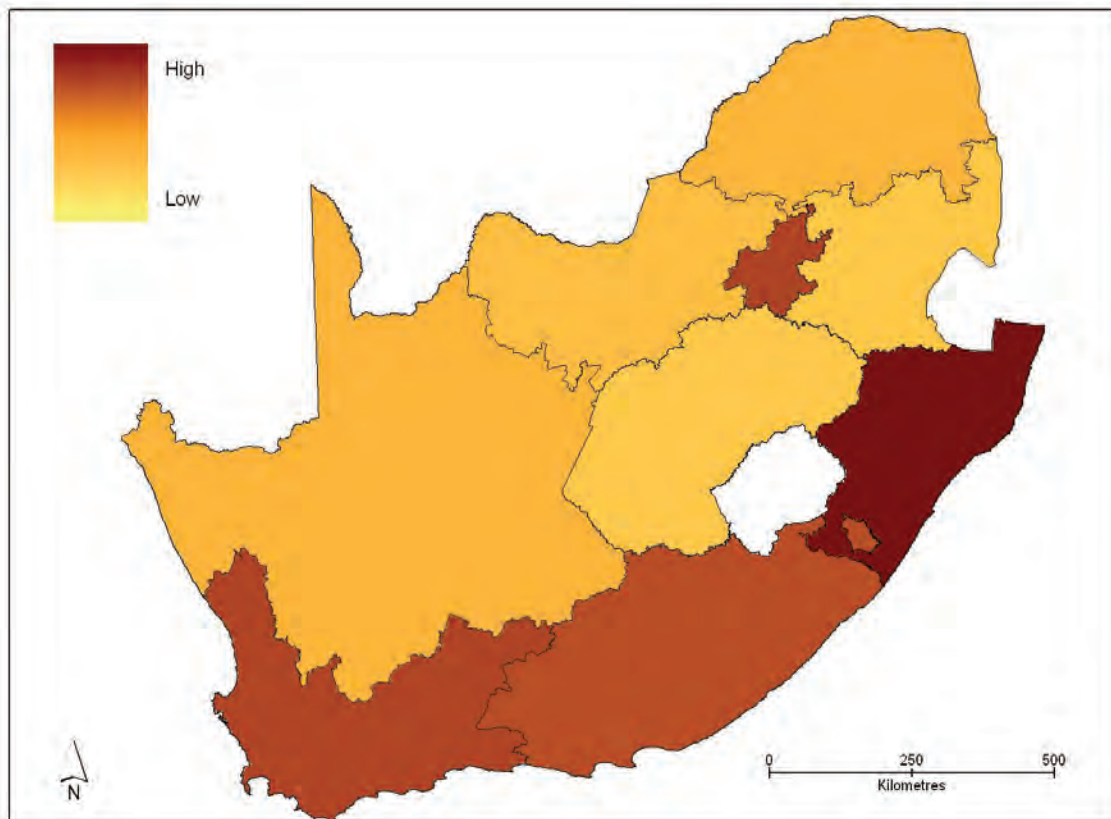


Figure 2-7 Prevalence of HIV positive rates by province

Considering the two preceding statistics as representing the potential sensitive subpopulation estimates, one would also need to consider the population densities in those areas, to get an indication of the numbers involved. Figure 2-8 represents the population densities from Statistics SA.

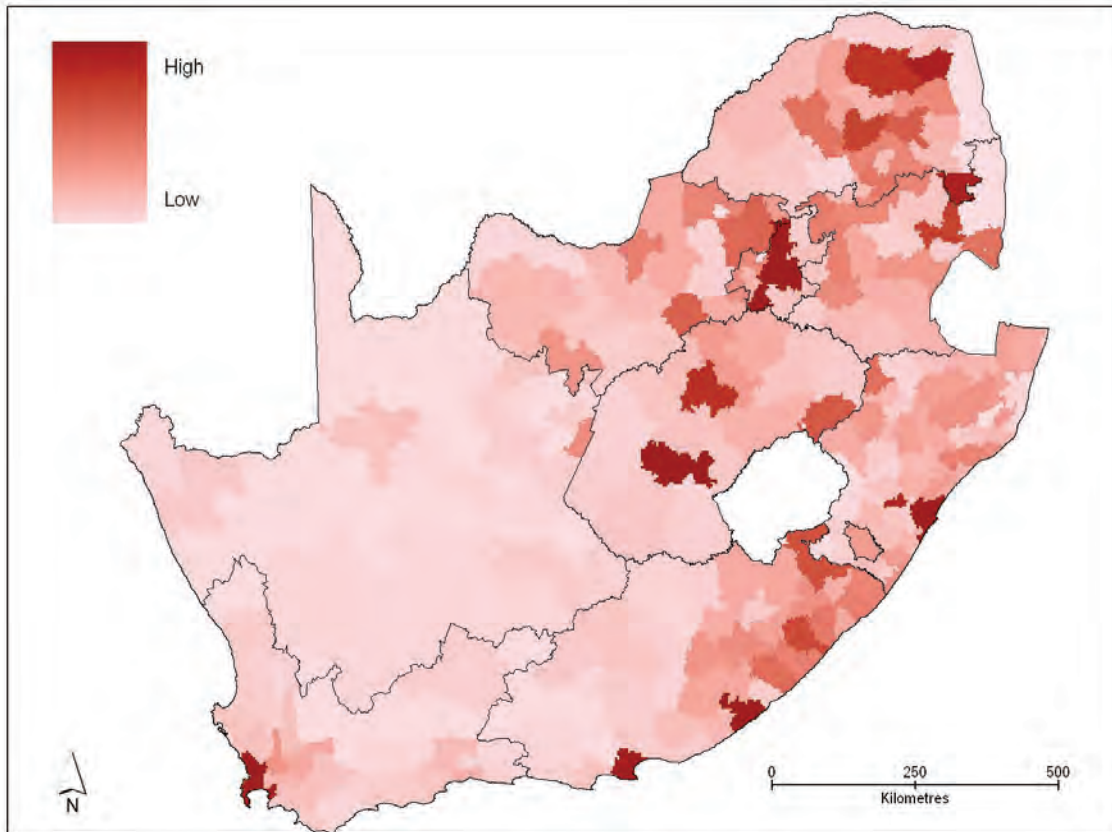


Figure 2-8. South African population density figures by district

Taking the two potential sensitive subpopulations into account together with the population densities, it can be seen that more of the potentially sensitive subgroups occur in the major centres in the eastern part of the country.

Figure 2-9, below, represents the combination of the poverty statistics (to represent malnutrition), HIV prevalence rates together with the population figures to provide an indication of the *potential high-risk areas of sensitivity to fluoride*.

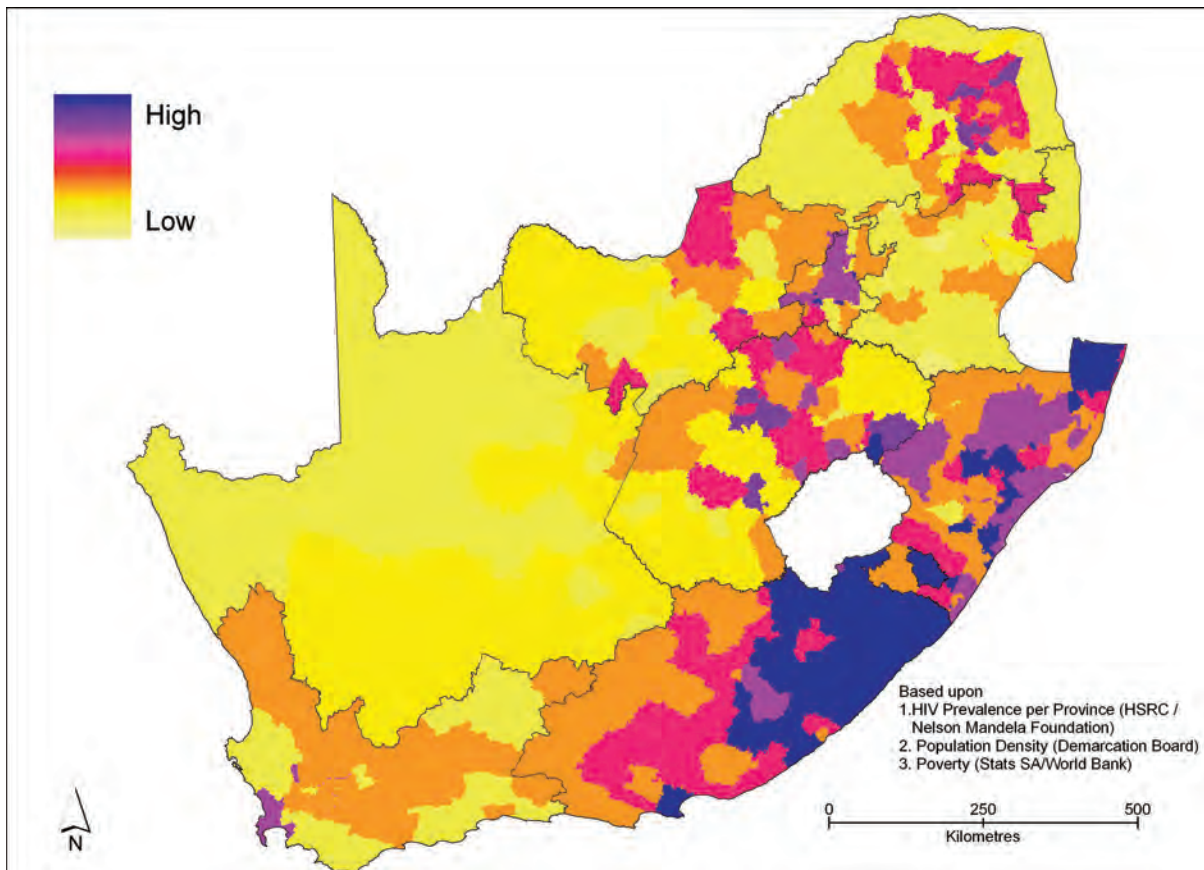


Figure 2-9. Areas of potential risk to sensitivity to fluoride, calculated using poverty, HIV prevalence and population statistics

The greatest numbers of potential sensitive subpopulations are found in the major cities in the Eastern Cape, and KwaZulu Natal as well as the Cape Metropole and Gauteng.

2.7 Conclusions

There are many uncertainties regarding the health effects of fluoride in general and water fluoridation in particular. The evidence for toxic effects including dental and skeletal fluorosis is well established. The evidence is not available to be able to establish the exact dose that other potential toxic effects occur. The evidence for carcinogenic effects is inconclusive as very little good quality research is available even though numerous studies have been published on the subject.

The York Review (McDonagh *et al*, 2000) concluded that there is little good quality research on the broader question of fluoride and health. This review has been received as being one of the better reviews carried out on the subject of water fluoridation.³ The United Kingdom's Medical Research Council Working Group looking at the subject (MRC, 2002) also concluded that there is "no firm evidence linking water fluoridation to

³ Professor Sheldon, the chair of the Advisory Group for the "York Review" wrote a letter soon after its release stating his concerns that the statements were being misrepresented. He stated that "the review did not show water fluoridation to be safe – but rather that the quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to high levels of fluorosis".

cancer, but the group recommended that an updated analysis of the data on fluoridation and cancer rates be carried out.

The York Review included an analysis of 26 international studies and indicated that water fluoridation results in a **14.6% improvement** in the percentage of caries-free children, with a medium improvement of 2.25 caries free teeth. Therefore, one can state that fluoride is beneficial in preventing caries. (McDonagh *et al*, 2000). According to the Center for Disease Control and Prevention of the United States, the maximum benefit of preventing dental caries is from topical application (CDC,1999).

It is agreed that fluoride is toxic, but the precise concentration at which the toxic effects are manifested in various groups is unknown. A great deal of information is available suggesting potential detrimental effects. The WHO (2002) states that there is a narrow range between intake associated with negative and beneficial effects. The evidence is not conclusive that fluoride is harmless at the doses originally thought to be harmless.

Most studies, when assessing water fluoridation did not take total exposure into account - total dietary intake of fluoride or ingestion of fluoride through ingestion of soil, dust or toothpaste is excluded from most studies. No studies (as far as could be established) took into account fluoride intake from any other pathway, such as inhalation of fluoride. Very little is known about true total exposure of fluoride, either here or in the rest of the world. However, using the WHO (2003) environmental levels and exposure data, a hazard index of 2 was calculated, indicating an exposure twice that considered to be safe resulting in potential harmful effects, such as dental fluorosis.

Research indicates that there is a possibility of fluoride being carcinogenic in humans, but this remains to be proven.

One of the conclusions from the York Review was that there was little evidence that water fluoridation reduced social inequalities (McDonagh *et al*, 2000). It was not clear from the review whether this finding can be extrapolated to developing country conditions such as found in South Africa where many people do not have access to either toothbrush or fluoride toothpaste.

South Africa has a very large potential sensitive subpopulation that may experience the detrimental effects of fluoride at the proposed water fluoridation concentration. There are many unknown factors with regards to the toxicity and carcinogenicity potential of fluoride and this may be exaggerated in the immuno-compromised.

In general, health risk assessments are meant to assist the relevant decision makers in weighing up the risks versus the benefits associated with a particular potential adverse affect – in this case water fluoridation. Different types of errors described earlier when testing hypotheses, are either "type I" or "type II" errors. An example of the hypothesis is that fluoride is safe. An attempt to decrease the type I error is accompanied in general by an increase in the other type of error. A compromise should be reached in favour of a limitation of the more serious error, also known as the 'precautionary principle'. In the context of this study, one would look at the consequences of making a type I error (*ie*, conclude that fluoride is not safe) versus the consequences of making a type II error, namely concluding that fluoride is safe. One would weigh up the consequences of these two types of errors to use in the decision making process.

2.8 Recommendations for future research

- High quality epidemiological studies need to be carried out to examine all the possible adverse health effects of fluoride and water fluoridation, taking into account accurate exposure assessments. (This is extremely costly and time-consuming and is intended as a general recommendation)
- An indication of total exposure to fluoride of South Africans is needed. This includes fluoride ingestion from food, food prepared with water containing fluoride, toothpaste and mouth rinses, soil / dust, and via inhalation.
- An assessment of the sensitivity to the toxic effects of fluoride of the immuno-compromised needs to be investigated, as this has serious implications on health policy and recommendations for HIV+ and Aids sufferers. (It may be necessary to recommend these individuals drink bottled water with low fluoride levels)

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CHAPTER THREE

ENVIRONMENTAL ISSUES

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M.J. van Veelen, BKS Consulting Engineers

3.1 Introduction

Return flows are the main driving force controlling the environmental impact of fluoridation. The contribution of effluent to base flow is a determining factor for peak concentrations. Chronic effects are governed by median conditions. The greatest change in river quality can be anticipated where current effluent fluoride concentrations are low since fluoridation will then add the greatest load. The presence of other sources of fluoride entering the river from natural or industrial sites can exacerbate the downstream impact. Adverse impacts can also be anticipated when evaporative concentration of salts occurs in semiarid or arid areas. Location is a crucial factor. Fluoridation will have no impact in instances when the ensuing effluent is discharged to marine outfalls. The greatest potential for problems is in inland river systems, especially those where significant cascading downstream water reuse occurs.

The natural environment, domestic, irrigation and industrial use can be affected.

Proper evaluation of potential impacts requires a good understanding of each river system and detailed information on effluent discharge rates and fluctuations in both natural and regulated river flows, as well as of effluent and river fluoride concentrations. Such an evaluation for the whole of South Africa is clearly beyond the scope this limited budget investigation. Effort therefore had to be concentrated on a few priority systems where the most significant impacts are likely to occur. Emphasis has been placed on areas where effluent return flows significantly contribute to streamflow and where background fluoride concentrations warrant closer attention.

The following river systems have been selected for examination:

- Vaal Barrage - Middle Vaal River
- Upper Crocodile River
- Msunduzi River
- Sand River
- Modder River
- Berg River
- Buffalo River
- Waterval River

The initial desktop impact evaluation carried out by Rand Water has received special attention, since this covers the most important development region and is also one of the few available South African impact assessments. Inferences have also been drawn from the findings of the DWAF's water quality situation assessment study of the Waterval River catchment.

3.2 Overview

3.2.1 Background Fluoride Levels

Median fluoride concentrations at DWAF surface water monitoring stations for the five-year period 1996 to 2000 are shown on one of the maps appended to this chapter. This divides the stations into three categories:

- Stations where the median fluoride concentration is below 0.5 mg/l
- Stations with median fluoride concentrations between 0.5 and 0.7 mg/l
- Stations where the median fluoride concentration exceeds 0.7 mg/l

The last category indicates areas where de-fluoridation may be required. But their relevance to the impact of fluoridation of water supplies depends on the relative magnitude of any upstream effluent discharges and the fluoride concentration of the water supplied to users contributing to the effluent discharge. For example, there are high fluoride concentrations in the upper Fish River catchment. However, the effluent discharges to this area are negligible so the high background levels are most likely attributable to geological factors and the general aridity of the catchment. High fluoride concentrations lower down the catchment would probably obviate the requirement for fluoridation, again negating the downstream impact.

3.2.2 Estimation of Downstream Quality

In the case of the Vaal Barrage-Middle Vaal River and parts of the Crocodile River systems the results of a preliminary impact assessment of fluoridation in the Rand Water Rand supply area have been used. Herold (2002) describes the methodology. This analysis is based on monthly effluent and river flow data, the current change in fluoride concentration from the raw water to effluent discharge and estimation of river losses between sampling points. While this preliminary methodology does not handle storage changes in major reservoirs well, it is considered to give an adequate initial estimate of the likely impact of fluoridation.

For other areas a much cruder assessment has been made based on the average effluent discharge, the median river flow and 5-years of fluoride data at key points in each river system.

The methodology used in this initial investigation is described in an appendix to this chapter.

3.3 Assessment system

3.3.1 Background

In order to adjudicate the significance of any changes in the fluoride concentrations in surface water bodies receiving treated wastewater; it is necessary to develop an assessment system. This assessment system has to take into account the various uses of water, as well as how users are affected by changes in the fluoride concentrations.

As the assessment done for this investigation is not site-specific, the assessment system has to be generic and can not take individual users into account. In this case different user groups are therefore considered. For this purpose the South African Water Quality Guidelines (1996) were consulted. With respect to fluoride, the following user groups are relevant:

Domestic use	:	Human health
Agriculture	:	Livestock watering and irrigation
Aquatic ecosystems	:	Animals that live in the water.

3.3.2 Principles

The effects of changes in fluoride concentrations can be immediate (acute effects) or only manifest themselves after a long period of exposure (chronic effects). The change in concentration that may result from the fluoridation of drinking water is not expected to result in acute effects, but rather in chronic effects. In this range the central tendency of the concentration is more important than the instantaneous concentration, and the statistical distribution of the individual measurements over time should be used to determine the fitness for use.

As water quality is not statistically normally distributed (a value or concentration can not be negative), non-parametric statistics are used to describe the statistical distribution of fluoride concentrations. The following parameters will be used in this assessment:

50th percentile: An indication of average conditions

75th percentile: The upper limit of the inter-quartile range, which indicates the upper limit of what a user will be exposed to on average

95th percentile: Indicative of extreme conditions of short duration. This should fall below acute levels.

Water quality can also not be described simply as “good” or “bad”, but as a gradual change from one to the other. The categories and descriptors that have been generally accepted are:

Ideal water quality where there is no effect even after continued use after a long time.

Acceptable water quality where only in rare instances some sensitive users may be affected after a long period of use.

Tolerable water quality where sensitive users may be affected after a long period of use.

Unacceptable water quality where there is a risk that chronic effects may occur.

The assessment system that will be used in this study considers the category in which the fluoride concentration falls, and also the duration as signified by the percentile value.

3.3.3 Guidelines

Table 3-1 is based on the South African water quality guidelines (all values in mg F/l).

Table 3-1 Fitness for use categories for Fluoride (mg/l)

Water use	Fitness for use category			
	Ideal	Acceptable	Tolerable	Unacceptable
Domestic Use	< 0.7	0.7 – 1.0	1.0 – 1.5	> 1.5
Livestock Watering	< 2.0	2.0 – 4.0	4.0 – 6.0	> 6.0
Irrigation*	< 2.0			> 15.0
Aquatic Ecosystems	< 0.75	0.75 – 1.5	1.5 – 2.54	> 2.54

NOTES: *On acid sandy soils fluoride concentrations should be maintained at less than 1 mg/l (SA Water Quality Guidelines, 1996)

From the above it is clear that domestic use represents the most sensitive user group, followed by aquatic ecosystems. The assessment system used for this study should therefore be based on these user groups.

For human health a fluoride value of 8 mg/l is also set that may never be exceeded.

The category (Ideal, Acceptable, Tolerable, Unacceptable) in which a water body can be classed, must be judged on average as well as extreme conditions. For this reason the 50th, 75th and 95th percentile cut-off limits should be specified.

In order for the water to be classed as ideal, the limit value for ideal should almost never be exceeded. This means that the 95th percentile value is set at the upper limit for ideal.

For acceptable conditions the upper limit for ideal can be exceeded some of the time, but the upper limit for acceptable should not be exceeded. The 95th percentile value is therefore set as the upper limit for ideal. The 75th percentile is also set as the upper limit for acceptable because there is no reason to set it at a lower limit. This becomes somewhat meaningless, as the 95th percentile and the median are the determining values.

For tolerable conditions the upper limit for tolerable should not be exceeded. The 95th percentile value is therefore set at the upper limit for tolerable, and no restriction is placed with respect to the other percentile values.

The fitness for use categories for irrigation are tentative and are dependent on the type of crop, soil type and irrigation application. Deciduous trees tend to store salts in their leaves where it builds up to unacceptable levels. The effect is well known with respect to chloride and boron. It is unlikely that fluoride at the levels that are considered will present a problem, but this needs to be investigated in some more detail. The long-term effect of fluoride in fertiliser on build up in irrigated soils and return flow also needs to be examined. This needs to be weighed against the impact of fluoridation, taking due account of the effective application rate.

For aquatic ecosystem health, the classification of the water body should also be considered. The proposed relationship between the classes (A, B, C or D) and the distribution of the concentration is shown in **Table 3-2**.

Table 3-2 Proposed ecological classes for fluoride (mg/l)

Class	Percentile upper limit		
	50%	75%	95%
A	0.75	0.75	0.75
B	0.75	1.5	1.5
C	1.5	1.5	2.54
D	2.54	2.54	2.54

As the class of the water sources that will be used in this study have not been determined yet, a Class B has been chosen as acceptable on the basis that a class A is unlikely to be set for highly impacted water bodies, while the long-term objective would be to maintain all water bodies in South Africa at least as a Class C.

3.3.4 Assessment System

Based on the foregoing, the assessment system that will be used for this study is as follows.

Table 3-3 Assessment system for fluoride (mg/l)

Class	Percentile upper limit		
	50%	75%	95%
Ideal	0.7	0.7	0.7
Acceptable	0.7	1.0	1.0
Tolerable	1.5	1.5	1.5
Unacceptable	Any other combination		

It should be noted that even the tolerable category will have a significant risk of undesirable effects, either on humans or the aquatic ecosystem, and is therefore cause for concern. Moreover, the **Table 3-3** should be viewed as a means of categorising a water body, rather than as defining a management objective.

3.3.5 Management Objective

It would be an exercise in brinkmanship to load the system with a pollutant to raise its concentration to the very limits of the acceptable range. Responsible management requires the setting of management objectives somewhat below the limits of acceptability. This is necessary to allow for future growth, unforeseen circumstances and the coarse nature of the current evaluation.

The purpose of this investigation is not to set such management objectives. However, a tripwire is required to determine if more detailed investigation is required. For this purpose a 30% buffer is proposed. Hence each of the values given in **Table 3-3** would be reduced by 30% to allow for a margin of error in the coarse assumptions and possible future growth. The preliminary management targets are given in **Table 3-4**.

Table 3-4 Preliminary management targets for fluoride (mg/l)

Class	Percentile upper limit		
	50%	75%	95%
Ideal	0.5	0.5	0.5
Acceptable	0.5	0.7	0.7
Tolerable	1.05	1.05	1.05
Unacceptable	Any other combination		

The upper limit of the Acceptable level (i.e. a median of 0.5 mg/l, and a 95 percentile value of 0.7 mg/l represent the tripwire level above which more detailed investigation is indicated.

3.4 Representative potential problem areas

Eight river systems have been selected for closer examination of the impact of fluoridation. These represent the major urban areas where effluent discharge makes a significant contribution to downstream river flow. They are also characterised by downstream river use.

The features of each system briefly sketched in the following sections. The locations of the catchments included in the assessment are depicted on one of the maps appended to this chapter.

3.4.1 Vaal Barrage – Middle Vaal River

Each year Rand Water delivers some $1200 \times 10^6 \text{m}^3$ of potable water to its users. During 2001 about $635 \times 10^6 \text{m}^3$ of treated sewage effluent was discharged from municipal wastewater treatment works. $362 \times 10^6 \text{m}^3$ of the municipal effluent were discharged to the Vaal Barrage catchment or to the Vaal River immediately downstream of the Vaal Barrage. This excludes the quantity discharged by industries such as Sasol 1, Iscor and Sappi, all of which also receive potable water from Rand Water. Sasol 1 discharges fluoride enriched effluent to the Vaal River downstream of Vaal Barrage, necessitating a minimum release from Vaal Barrage to dilute the downstream river system.

This effluent makes a very significant contribution to runoff in the Vaal River and its tributaries draining the Vaal Barrage catchment. Consequently concerns were raised at the possible impact of fluoridation on the quality of the receiving rivers, especially since high fluoride levels are already experienced in some localities. These include the Groot Rietspruit near Loch Vaal and the Middle Vaal River. Evaporative concentration in the Vaal River is a further cause for concern, especially during base flow conditions which prevail for two-thirds of the year when there is little dilution from catchment runoff. Arising from these concerns Rand Water undertook a preliminary desktop investigation into likely impacts (Herold, 2002). Rand Water abstracts part of its water supply from Vaal Barrage. In 1995 Parys abstracted $6 \times 10^6 \text{m}^3$, from the Vaal River downstream of Vaal Barrage, Midvaal Water abstracted $65 \times 10^6 \text{m}^3$ and Sedibeng Water $73 \times 10^6 \text{m}^3$.

Figure 3-1 is a diagrammatic representation of the catchment and the downstream portion of the Vaal River included in the Rand Water investigation.

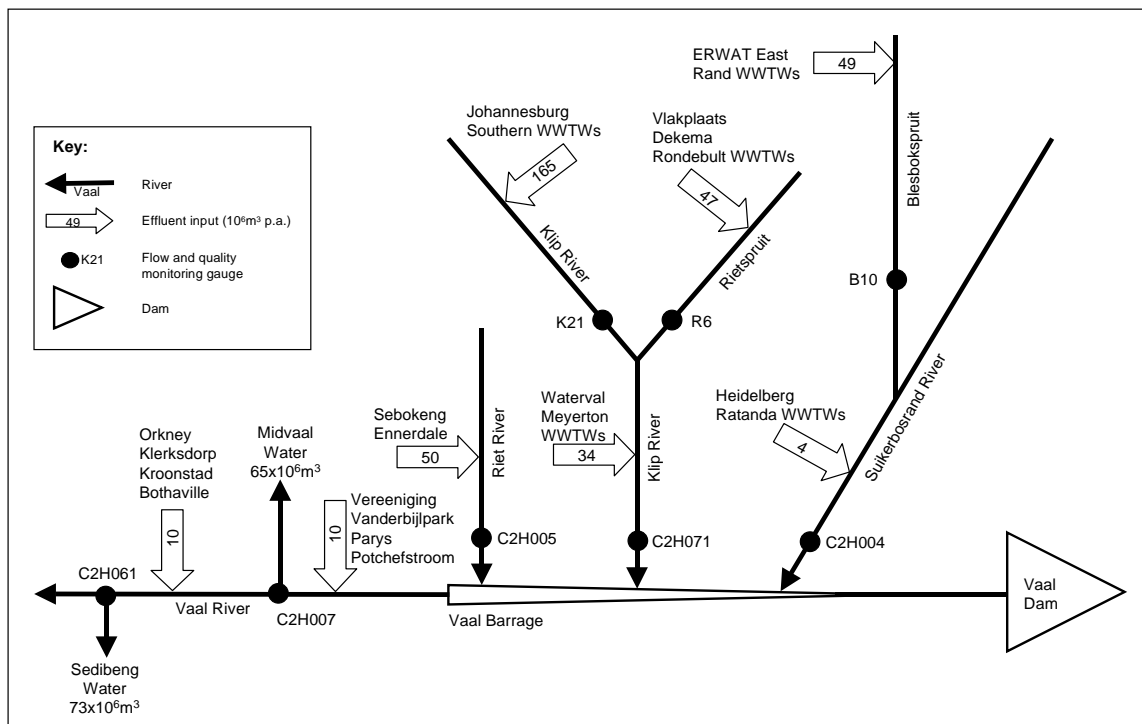


Figure 3-1 Diagrammatic representation of Vaal Barrage – Vaal River system

3.4.2 Upper Crocodile River

Rand Water is also the main supplier of potable water to users in the upper Crocodile River catchment, with a municipal effluent discharge of $281 \times 10^6 \text{ m}^3$ to the local river system. This excludes return flows from industries, such as the Modderfontein chemical complex, Kelvin power station and Rooiwal power station. Elevated fluoride concentrations already occur at several points in the river system. In some cases the high concentrations are probably attributable to local pollution sources. Natural sources, cascading water use and increasing aridity in a downstream direction exacerbate these.

Figure 3-2 is a diagrammatic representation of the upper Crocodile River system.

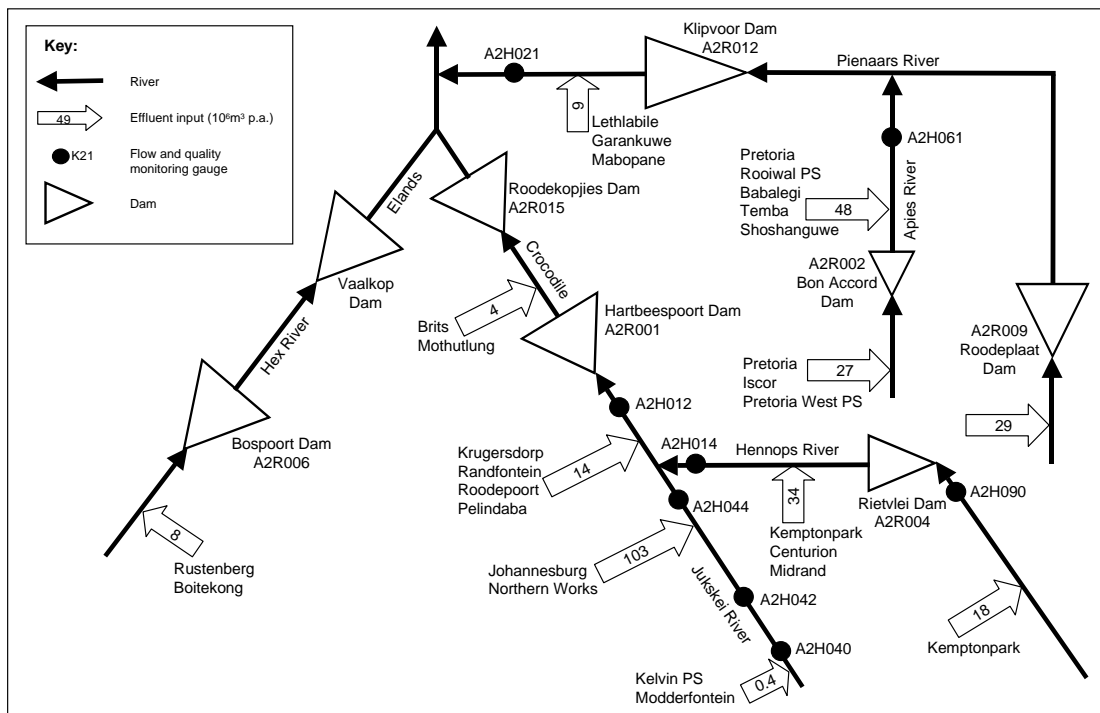


Figure 3-2 Diagrammatic representation of Upper Crocodile River system

3.4.3 Msunduzi River

The Msunduzi River below the Darvill wastewater treatment works was selected for examination in the Mgeni Water system. This river reach was chosen since the Msunduzi River is an inland river where the Pietermaritzburg return flow makes a significant contribution to the base flow. Below its confluence with the Mgeni River a substantial abstraction is drawn from Inanda Dam to supply the Wiggins water works. Further information was obtained from Umgeni Water (Ramjatan et. al, 2000) and an MSc thesis by A Ramjatan (2002)

Figure 3-3 is a diagrammatic representation of the Msunduzi River system.

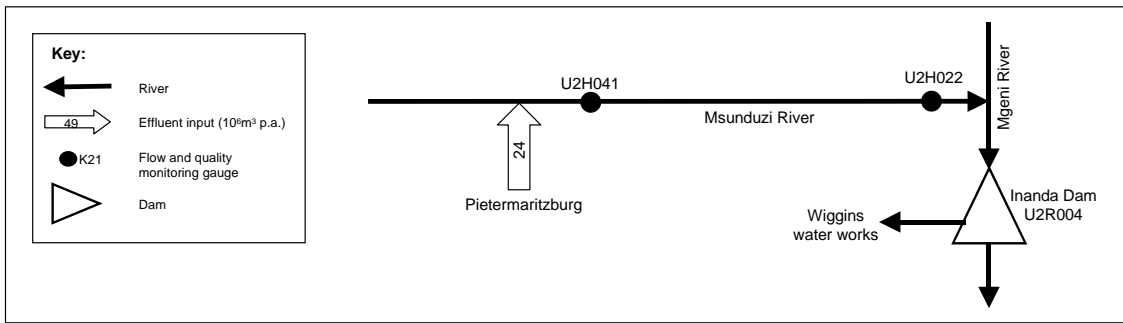


Figure 3-3 Diagrammatic representation of Msunduzi River system

3.4.4 Sand River

Effluent return flows from Welkom and Virginia in the Freestate Goldfields area could affect fluoride levels in the Sand River.

Figure 3-4 is a diagrammatic representation of the Sand River system.

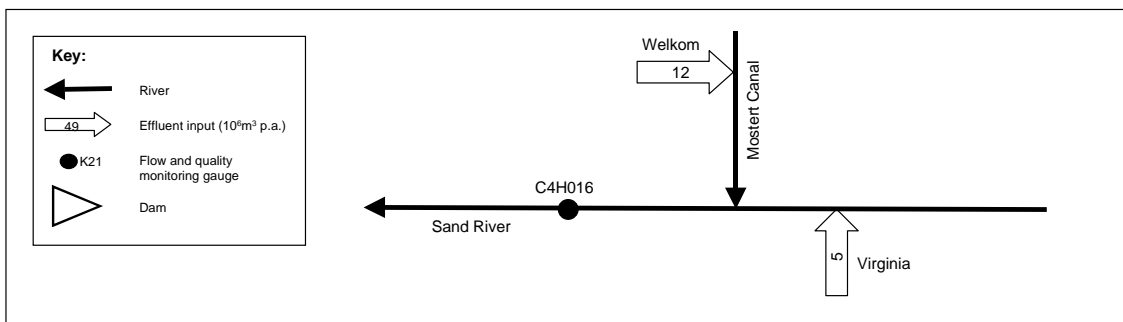


Figure 3-4 Diagrammatic representation of Sand River system

3.4.5 Modder River

The reach of the Modder River between Bloemfontein and Krugersdrif Dam is likely to be affected by effluent discharges from Bloemfontein, Botchabelo and Thaba 'Nchu. Individual tributaries between the wastewater treatment works and the Modder River should be even more affected, but fluoride monitoring data in these river reaches is too sparse to make a meaningful assessment. Unfortunately there was also insufficient fluoride data at gauge C5H015 in the Modder River upstream of Krugersdrif Dam. Hence it was only possible to carry out an analysis using the monitoring record at Krugersdrif Dam itself. This is less than ideal since the results will be affected by storage attenuation in Krugersdrif Dam. This site is also remote from the effluent sources where incremental catchment runoff might have diluted the impact that could be expected further up the Modder River.

Figure 3-5 is a diagrammatic representation of the affected portion of the Modder River.

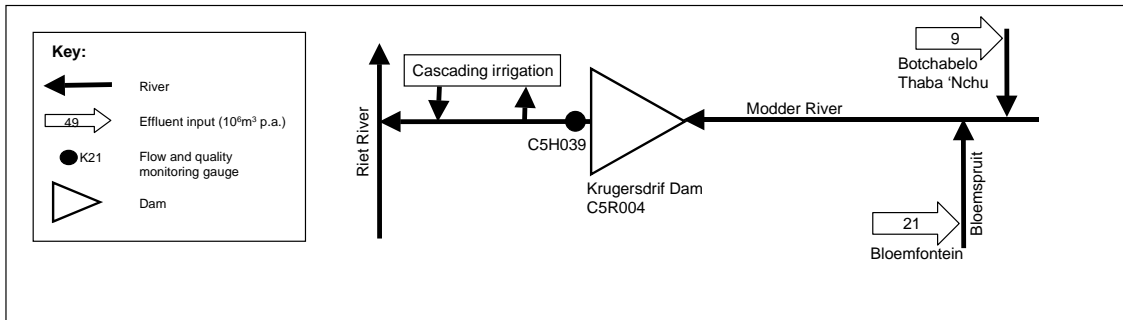


Figure 3-5 Diagrammatic representation of Modder River system

3.4.6 Berg River

The reach of the Berg River downstream of Paarl and Wellington has been investigated. Further downstream diluting water enters the Berg River from the Voëlvlei Dam upstream of the Misverstand Weir, from which water is diverted to supply to Saldanha. Extensive irrigation occurs along the Berg River. Water releases to supply irrigation requirements tend to dilute the effect of the irrigation return flows.

Figure 3-6 is a diagrammatic representation of the affected portion of the Berg River

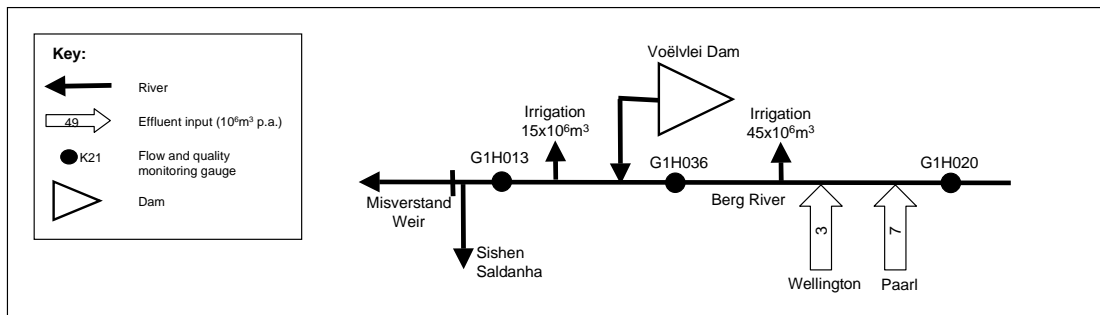


Figure 3-6 Diagrammatic representation of part of Berg River system

3.4.7 Buffalo River

Effluent from King Williams Town and Zwelitsha enters the Buffalo River upstream of the Laing Dam. This dam is also the source of supply to these regions. Hence there is a feedback loop that could affect supply quality during drier periods.

Figure 3-7 is a diagrammatic representation of this portion of the Buffalo River.

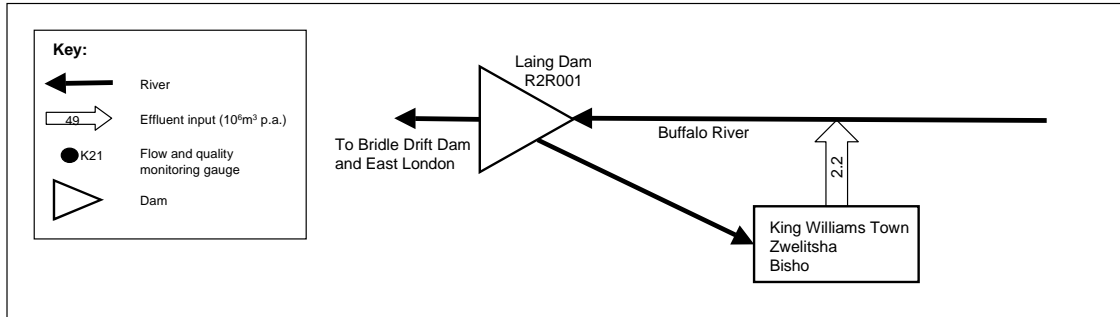


Figure 3-7 Diagrammatic representation of part of the Buffalo River system

3.4.8 Waterval River

The DWAF carried out a water quality situation assessment of the Waterval River catchment in 1992 (Stewart Scott, 1992). This study showed high fluoride values at the monitoring points shown in **Figure 3-8**.

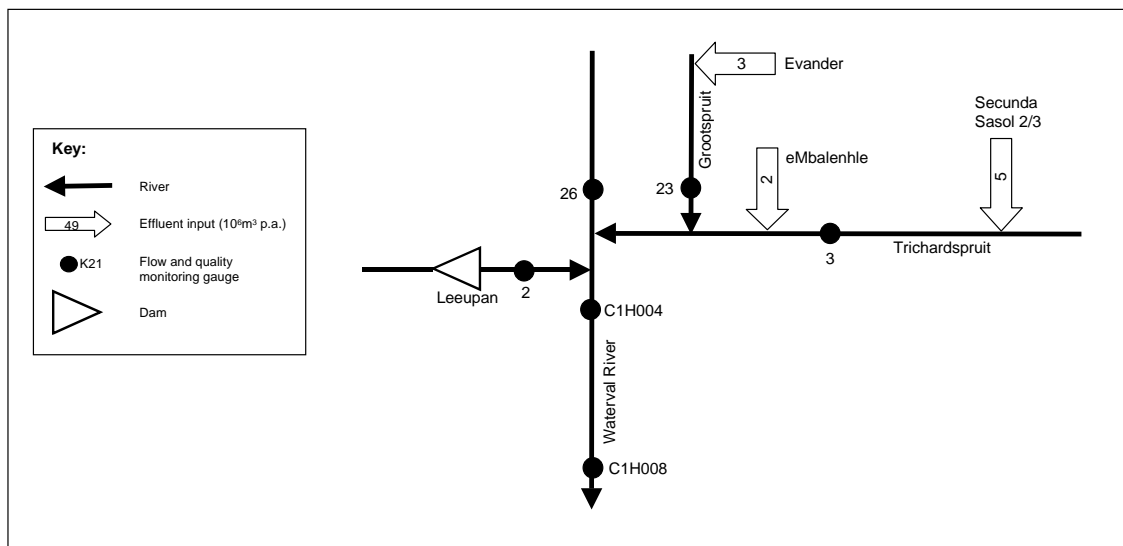


Figure 3-8 Diagrammatic representation of upper Waterval River system

3.5 Impact of Fluoridation

An initial desktop assessment of the impact of fluoridation has been made directly for much of the area supplied by Rand Water (Herold, 2002). Umgeni Water has also carried out impact assessments (Ramjatan et. al, 2000) and (Ramjatan, 2002). For other selected areas the methodology described in Section 3.2 and the appendix has been used to make a coarse initial assessment. In the case of the Waterval River and part of the Crocodile catchment the resources of the study did not permit more than making inferences from the results of earlier investigations. The results of all of these investigations are summarised in the following sections.

3.5.1 Vaal Barrage – Middle Vaal River

A summary of the 50%, 75% and 95% fluoride concentrations at key points in the Vaal Barrage catchment and in the Middle Vaal River is given in **Table 3-5**. The locations of these monitoring stations are shown in **Figure 3-1**. The values for the Vaal Barrage catchment are based on the results of a desktop investigation carried out by Rand Water taking account of monthly flow and fluoride data for the 11-year period ending December 2001 (Herold, 2002). The Midvaal Water (C2H007) and Sedibeng Water (C2H061) results are based on shorter records.

Values that exceed the management objective for fluoride given in **Section 3.3.5** are shown in bold in **Table 3-5**

Table 3-5 Fluoride percentile values in Vaal Barrage – Middle Vaal

Station	Before fluoridation			After fluoridation to 0.7 mg/l		
	50%	75%	95%	50%	75%	95%
B10 – Blesbokspruit	0.31	0.34	0.42	0.60	0.79	1.12
C2H004 - Suikerbosrand	0.28	0.32	0.39	0.53	0.67	1.09
K21 - Upper Klip River	0.33	0.37	0.43	0.68	0.74	0.80
R6 – Rietspruit	0.33	0.37	0.43	0.51	0.55	0.60
C2H071 - Klip River	0.38	0.32	0.39	0.54	0.61	0.72
C2H005 - Groot Riet River	0.63	0.69	0.84	0.73	0.82	0.99
C2H007 - Vaal at Midvaal	0.33	0.39	0.46	0.50	0.64	0.79
C2H061 – Vaal at Sedibeng	0.54	0.60	0.64	0.73	0.79	0.84

This indicates that the median (50%) fluoride target, which is indicative of the long-term exposure of users, was historically exceeded in the Groot Rietspruit (C2H005) and in the Vaal River at the Sedibeng Water intakes (C2H061). The 95% peak fluoride concentration objective was also exceeded in the Groot Rietspruit. After fluoridation the median target would be exceeded at all of the key points. This indicates a possible danger of chronic effects occurring in this region. Although higher, the 75% and 95% peak fluoride concentrations do not appear to threaten of acute impacts.

Fluoridation would present a danger of moving the Blesbokspruit (B10) and the Suikerbosrand (C2H004) into the Unacceptable range (i.e. 95% peak concentrations above 1.05 mg/l given in **Table 3-4**).

The impact on the Middle Vaal River (C2H007 and C2H061) is of particular concern since Midvaal Water and Sedibeng Water supply water to large populations. These include large numbers of underground mine workers, who work in high humidity hot environments that force abnormally high water consumption (about three times the per capita consumption of other inhabitants). Such workers will therefore be placed at high risk since they will be exposed to three times the amount of fluoride through consumption of water.

Moreover, the period covered in the analysis for the Middle Vaal River was abnormally wet and water demands were also substantially lower than the system yield. This permitted continual operation of the Vaal Barrage dilution option with consequent very high base flows in the Middle Vaal River. Unacceptable conditions arose even with these exceptional dilution factors under base flow conditions (with the *minimum* monthly base flow at least twice as high as required to meet downstream

requirements). Significantly worse conditions can therefore be expected during more restrained (even normal) conditions, especially in future years when water requirements grow to more nearly match system yield.

The elevated fluoride levels primarily threaten domestic use (with some $138 \times 10^6 \text{m}^3$ of potable water supplied to the strategic North-West province and Freestate Goldfields) and the natural environment.

The Rand Water analysis did not extend beyond Sedibeng Water. However, the data for the last five years ending September 2002 shows historical median fluoride concentrations in the Bloemhof Dam and other points in the Vaal River down to the Douglas Weir that are close to those at the Sedibeng Water intakes. This implies that storage attenuation in the Bloemhof Dam and dilution by the small incremental catchment runoff is outweighed by evaporative concentration in the arid Lower Vaal River. It is therefore reasonable to expect that fluoridation by Rand Water would lead to similar deterioration in downstream fluoride concentrations. This could adversely affect the domestic water supply to Kimberly, Vaal-Gamagara, Douglas and other smaller communities ($30 \times 10^6 \text{m}^3$), the biggest irrigation scheme in South Africa at Vaalharts (some 36 000 ha), riparian irrigation along the Vaal and Harts Rivers (19 400 ha) and the natural environment.

3.5.2 Upper Crocodile River

Fluoridation can be expected to have a large impact on fluoride concentrations in the rivers of the upper Crocodile catchment because treated effluent makes up a large proportion of the mean annual runoff (MAR). The general aridity of the catchment together with evaporative concentration in dams is expected to increase these problems.

Only the Rietvlei Dam (A2H090) and the Hartbeespoort Dam (A2R001) were assessed by Rand Water at the same level of detail as for the Barrage catchment using data for the 11-year period ending December 2001 (Herold, 2002). The 50%, 75% and 95% results are given in **Table 3-6**.

Table 3-6 Fluoride percentile values in Rietvlei and Hartbeespoort Dams

Station	Before fluoridation			After fluoridation to 0.7 mg/l		
	50%	75%	95%	50%	75%	95%
A2H090 – Rietvlei Dam	0.32	0.42	0.53	0.61	0.72	0.89
A2R001 – Hartbeespoort Dam	0.46	0.59	0.81	0.80	0.90	1.09

At Hartbeespoort Dam the median fluoride concentration would deteriorate from acceptable to unacceptable conditions. The elevated historical peak concentrations in Hartbeespoort Dam are attributable to pollution sources in the upper Jukskei River.

The analysis for A2H090 is based on a river monitoring point just upstream of the Rietvlei Dam. The effect of storage attenuation in the dam was not determined. The analysis for the Hartbeespoort Dam was based on the dam outlet. The methodology used does not deal rigorously with storage attenuation in the Dam, but is considered to give a reasonable coarse estimate of the long-term effect.

Abnormally wet conditions have distorted fluoride concentrations during the latter half of the record. During this period the 24-month moving mean inflow to the Hartbeespoort Dam was over 3.7 times higher than the natural mean annual runoff into this 1.2 MAR capacity dam. Despite this enormous dilution the calculated median fluoride concentration still came to 0.8 mg/l. This implies an even higher median during drier more normal conditions and during droughts.

Pretoria derives part of its water supply from the Rietvlei Dam and Brits and Cosmos are supplied from the Hartbeespoort Dam. Riparian irrigation (about 8700 ha) takes place along the Hennops, Jukskei and Crocodile Rivers in this area.

Irrigators below the Hartbeespoort Dam have just changed from tobacco to citrus. The build-up of fluoride in the leaves can shorten the economic life of these deciduous trees. Even for these abnormally wet conditions the median concentration is already high enough to present problems on acid sandy soils. While the median fluoride concentration was below the irrigation management target of 1.4 mg/l (70% of the fitness for use category) for neutral to alkaline soils, higher concentrations can be anticipated during more typical drier conditions.

The Rand Water study did not include analyses of the effect of fluoridation at other monitoring stations of the upper Crocodile River system. However, historical fluoride concentrations were examined (Herold, 2002).

Historical fluoride concentrations in the upper Crocodile River down to the Roodekopjies Dam are given in **Table 3-7**.

Table 3-7 Observed fluoride percentile values in Crocodile River sub-system

Station		Before fluoridation		
Code	Description	50%	75%	95%
A2H040	Upper Jukskei River	2.34	3.06	4.40
A2H042	Jukskei River	1.67	2.17	3.04
A2H044	Jukskei River below Johannesburg Northern Works	0.82	1.16	1.56
A2H012	Crocodile River above Hartbeespoort Dam	0.54*	0.78*	1.04*
A2R001	Crocodile River at Hartbeespoort Dam	0.53	0.67	0.87
A2R015	Crocodile River at Roodekopjies Dam	0.71	0.80	0.94

Note: * The concentrations in the Hartbeespoort Dam differ from those in Table 3.2 because the data spans a longer period to provide sufficient overlap with other stations.

Direct comparisons between the stations given in **Table 3-7** are problematic, since the available record for each station covers varying time spans. However the following conclusions, which are supported by time series plots, can be drawn.

- The upper Jukskei River is already seriously polluted, with all three stations in the Unacceptable range. Even the dilution of the large Johannesburg Northern Works fails to reduce fluoride concentrations to acceptable conditions.
- Storage attenuation (which includes the trapping of flood flows) made little difference to median fluoride concentrations in the Hartbeespoort Dam. Even the 95% peak was reduced by only 16%.
- The median fluoride concentration in the Roodekopjies Dam is substantially (33%) higher than that in the Hartbeespoort Dam. In the absence of significant point inputs this shows that evaporative concentration plays a bigger role than dilution by the incremental catchment runoff. This could indicate continuing impact far down the Crocodile River, where users are highly dependent on this water source.
- The median fluoride concentrations at all of the stations are well above that of the sewage effluent. (Rand Water supplies water at 0.18 to 0.2 mg/l, with very little increase expected for predominantly

domestic effluent.) This implies that the sewage effluent is currently a very substantial diluter of fluoride in this catchment.

Fluoridation of the Rand Water supply would substantially reduce the dilution currently afforded by the treated sewage discharges, which would increase in concentration by about 0.5 mg/l (from 0.2 mg/l to 0.7 mg/l). This would even affect the upper Jukskei River, since the Kelvin power station uses treated effluent from the Johannesburg Northern Sewage Works. The cooling circuit blow down water is then discharged to the Jukskei River. Hence not only will the fluoride concentration of the intake to this entity be increased directly; it will be multiplied by evaporative concentration in the cooling cycle. The Modderfontein factory also receives its water supply from Rand Water.

It is therefore concluded that fluoridation of the Rand Water supply will lead to severe fluoride problems in the Jukskei, Hennops and Crocodile River down to and beyond the Roodekopjes Dam.

Historical fluoride concentrations in the Pienaars River are given in **Table 3-8**.

Table 3-8 Observed fluoride percentile values in the Pienaars River

Station		Before fluoridation		
Code	Description	50%	75%	95%
A2R009	Pienaars River at Roodeplaat Dam	0.33	0.39	0.47
A2R002	Apies River at Bon Accord Dam	0.36	0.43	0.57
A2H061	Apies River	0.40	0.47	0.56
A2R012	Pienaars River at Klipvoor Dam	0.48	0.54	0.62
A2H021	Lower Pienaars River	0.58	0.65	0.76

Again it can be seen that the pre-fluoridation median concentrations are all larger than the Rand Water supply concentration of 0.18 to 0.2 mg/l. The observed values already reflect considerable dilution by sewage effluent, since sewage effluent comprises a large proportion of the MAR at these points (35% to 75% of the MAR). It follows that fluoridation of the Rand Water supply will substantially increase the fluoride concentrations. (An approximate estimate based on the calculated increase in fluoride concentration at Hartbeespoort Dam and the percentage contributions of effluent flow to MAR indicate median concentrations at Bon Accord and Klipvoor Dams of about 0.8 mg/l.)

3.5.3 Msunduzi River

The methodology described in Section 3.2 was used to estimate the 50%, 75% and 95% fluoride concentrations at key points in the Msunduzi River system. The results are shown in **Table 3-9**.

Table 3-9 Fluoride percentile values in Msunduzi River system

Station	Observed before fluoridation*			After fluoridation to 0.7 mg/l*		
	50%	75%	95%	50%	75%	95%
U2H041	0.11	0.14	0.18	0.24	0.27	0.31
U2H022	0.16	0.17	0.20	0.26	0.27	0.30
U2R004	0.17	0.21	0.32	0.21	0.25	0.26

NOTE: * These are very approximate values based on a few values provided verbally by Umgeni Water from their database (Simpson, 2003). More comprehensive data over a longer period could be obtained from this source for more detailed investigation.

Table 3-9 shows that fluoridation of the water supplied to Pietermaritzburg is not expected to lead to fluoride problems in the Msunduzi River. However, this evaluation is based on a very short sample record that was obtained verbally from Umgeni Water's data base for a short period from September 2002 to January 2003 (Simpson, 2003). It is therefore deemed wise to firm up on this initial analysis by using a longer water quality record. Thereafter a final decision can be made as to whether or not a more detailed investigation is warranted.

Investigations carried out by Umgeni Water (Ramjatan *et al*, 2000 and Ramhjatan, 2002) have indicated other areas in the Umgeni Water supply system where high fluoride concentrations have been observed. These include the Mshazi, Kwanyuswa, Kwa Ngcolosi, Mshwati and Mgozhongweni rivers, many of which are small streams that may not be significantly impacted by fluoridation and where local water use is limited. However, a more thorough understanding of the local situation is required before definite conclusions can be drawn. The review described in this report should therefore be extended to other parts of the Umgeni Water system before finalising the priority of areas requiring more detailed investigation.

3.5.4 Sand River

Estimated 50%, 75% and 95% fluoride concentrations at key points in the Sand River system are shown in **Table 3-10**.

Table 3-10 Fluoride percentile values in Sand River

Station	Observed before fluoridation			After fluoridation to 0.7 mg/l		
	50%	75%	95%	50%	75%	95%
C4H016	0.31	0.33	0.42	0.92	0.94	1.03

NOTE: * During the 5-year period considered the flow record at station C4H016 was very short. Time did not permit searching for a longer record.

Table 3.10 shows that fluoridation of the water supplied to Virginia and Welkom could increase the median fluoride concentration in the Sand River downstream of Welkom from 0.31 mg/l to 0.92 mg/l. This would exceed the acceptable limit. However, only a short flow record was available at station C4H016 for the 5-year period covered by the investigation. It is not clear whether this is due to malfunctioning of the weir recorder or time delay in the availability of the record. Effort should be made to obtain a fuller flow record, including the possibility of considering a different analysis period.

No significant domestic and irrigation use of the Sand River water takes place between Welkom and the Sand-Vet confluence since these demands are met from the irrigation canals originating from the Allemanskraal Dam. 1300 ha irrigation and domestic water use by Hoopstad does occur in the lower Vet River below the Sand-Vet confluence and the Bloemhof Dam. The effect of fluoridation on the lower Vet River will be considerably reduced by tail water releases from the irrigation canals, including the release made to meet the lower Vet River irrigation demands that form part of the Sand-Vet irrigation scheme. However, during previous severe drought conditions both the Allemanskraal Dam and the Erfenis Dam have emptied, resulting in cessation of the canal flows for irrigation use. During such conditions the sewage effluent flow would become the dominant source of water in the lower Vet River. Since such occurrences can span several months or even one or two years, the exposure can be considered relatively long-term for many vertebrate organisms.

3.5.5 Modder River

Estimated 50%, 75% and 95% fluoride concentrations at key points in the Modder River system are shown in **Table 3-11**.

Table 3-11 Fluoride percentile values in Modder River at Krugersdrif Dam

Station	Observed before fluoridation			After fluoridation to 0.7 mg/l		
	50%	75%	95%	50%	75%	95%
C5H039 dam downstream weir (average outflow)	0.29	0.32	0.37	0.47	0.50	0.55

Table 3-11 shows that fluoridation of the water supplied to Bloemfontein, Botchabelo and Thaba 'Nchu would not result in exceedance of the fluoride management target in the Modder River at the Krugersdrif Dam assuming average dam outflow conditions. However, this estimate does not account for longer-term climatic variations during which higher concentrations can arise during prolonged drought sequences.

Conditions in the Krugersdrif Dam under-estimate the change likely to occur in the Modder River upstream of this dam. This is because the median concentration in the river upstream of the dam will be determined by base flows, during which the effluent contribution will be more dominant. Moreover, the impact on upstream portions of the Modder River and affected tributaries such as the Bloemspruit will be more pronounced since the incremental catchment runoff is smaller.

Higher fluoride concentrations can also be expected in the Modder River downstream of the Krugersdrif Dam. Considerable concentration of salts occurs in this river reach due to cascading irrigation abstraction and return flow and evaporative concentration in a series of weirs formed by dolerite dykes intersecting the river.

3.5.6 Berg River

Estimated 50%, 75% and 95% fluoride concentrations at key points in the Berg River system are shown in **Table 3-12**.

Table 3-12 Fluoride percentile values in Berg River

Station	Observed before fluoridation			After fluoridation to 0.7 mg/l		
	50%	75%	95%	50%	75%	95%
Below Wellington	0.11	0.12	0.15	0.33	0.24	0.37
G1H036 at Herman	0.12	0.14	0.16	0.21	0.23	0.25
G1H013 at Drieheuwels	0.12	0.14	0.18	0.19	0.21	0.25

Table 3-12 shows that fluoridation of the water supplied to Paarl and Wellington could increase the median fluoride concentration in the Berg River below Wellington from 0.11 mg/l to 0.33 mg/l. The 95% peak concentrations would be only slightly higher. The limited impact is attributable to relatively large downstream irrigation use that is met from natural runoff supplemented by regulated release from the Tweewaterskloof Dam. Further downstream the change attributable to fluoridation is even lower. It therefore appears that the impact on users and the natural environment should be slight. This can be

stated with high confidence for median conditions, which will determine the long-term exposure. However, a time series of flow rates was not examined. The peak fluoride concentrations may therefore be under-estimates. Higher peak concentrations can be expected to occur towards the end of summer when irrigation requirements are low and river flows are low. The aridity of the area could then also lead to evaporative concentration down the river system. The entry of inflow from the Voëlsvlei Dam results in considerable dilution of the Berg River at G1H013, with the result that problematic fluoride concentrations are not expected to occur at the Misverstand diversion weir, from which water is transferred to Saldanha.

3.5.7 Buffalo River

Estimated 50%, 75% and 95% fluoride concentrations in the Buffalo River Laing Dam are shown in **Table 3-13**.

Table 3-13 Fluoride percentile values in Buffalo River

Station	Observed before fluoridation			After fluoridation to 0.7 mg/l*		
	50%	75%	95%	50%	75%	95%
R2R001 Laing Dam (average outflow)	0.21	0.22	0.26	0.22	0.23	0.27

Table 3.13 shows that fluoridation of the water supplied to King Williams Town and Zwelitsha would result in insignificant increase of the fluoride concentrations in the Buffalo River at the Laing Dam. Consequently the impact on the downstream East London area should also be negligible. These analyses do not take any account of the feedback loop. However, this effect should be limited since the abstraction for town and industrial use is only 10% of the dam's MAR and the return flow only 3% of MAR. The feedback loop is therefore only very partial. Evaporative concentration in the dam during prolonged drought sequences should also have limited effect since the dam is only 27% of MAR. This means that during most years it should spill one or more times.

It is therefore reasonable to assume that fluoridation will have little impact on fluoride levels in Laing Dam and the towns supplied from it.

3.5.8 Waterval River

The DWAF water quality situation analysis of the Waterval River (Stewart Scott, 1992) included assessment of the fluoride concentrations at key points in the river system for the two-year period ending September 1989. These results are summarised in **Table 3-14**.

Table 3-14 shows high median concentrations at several points in the system. Fluoridation of the water supply would lead to increased concentrations in the effluent from Sasol/Secunda eMbalenhle and Evander.

Table 3-14 Observed fluoride percentile values in Waterval River catchment

Station		Before fluoridation		
Code	Description	50%	75%	95%
3	Trichardspruit above eMbalenhle	1.0	NS*	2.4
23	Grootspruit below Winkelhaak, Braken and Kinross gold mines	0.6	NS	5.8
2	Tributary of Waterval River below Leeupan	0.5	NS	5.7
26	Waterval River at Leslie Gold Mine	0.5	NS	5.7
C1H004	Upper Waterval River at Roodewal weir	1.1	NS	1.8
C1H008	Lower Waterval River above confluence with Vaal	0.7	NS	1.4

Notes: * Not specified

The small tributary entering Leeupan would be unaffected by fluoridation as there is no significant upstream municipal effluent source. Little effect should be apparent in the upper Waterval River at Station 26, as the domestic effluent discharge from the Leslie gold mine is relatively small. However, most of the domestic water supply to the towns of Leslie, eMbalenhle and Secunda is from Rand Water. Hence fluoridation to 0.7 mg/l could be expected to increase the effluent fluoride concentration of these effluent sources by about 0.5 mg/l. This would substantially diminish the dilution of pollution sources in the Trichardspruit (station 3), the Grootspruit (station 23) and the Waterval River (C1H004 and C1H008).

More recent flow and water quality data has not been assessed, therefore any significant changes in water quality will not be reflected. But large significant increases in effluent flow rate will have occurred over the last decade, especially at eMbalenhle, which only started discharging effluent 2 years before the situation assessment was carried out.

3.5.9 Other Potential Problem Areas

The constraints of this overview did not permit evaluation of other areas. Those that may deserve attention include:

3.5.9.1 Molopo River

The Molopo River is extremely arid. Part of the supply to the greater Mafikeng area is from dolomitic aquifers to the east. More recently the Modimola Dam was built to supply water from downstream of this area. A partial feedback loop exists since this dam receives effluent from its supply area. However, increasing fluoride levels in the Modimola Dam will only be partially regulated by a reducing need to fluoridate the supply water. This is because the water supplied from the Modimola Dam only reaches the western portion of the greater Mafikeng area. The larger eastern portion that is supplied from groundwater resources will continue to require fluoridation to maintain a supply concentration of 0.7 mg/l. Hence increased fluoride loads will continue to enter the Modimola Dam. The severe aridity and poor basin shape of the dam would result in significant evaporative concentration, especially during dry sequences.

Since the Modimola Dam cuts off most of the runoff to the downstream Disaneng Dam, further severe evaporative concentration can be anticipated. This was found to be the case for salts when the Modimola Dam was being investigated. Similar mechanisms should also be applicable for fluoride.

3.5.9.2 Cowie River

Effluent from Grahamstown is discharged to the Cowie River. Fluoridation of Grahamstown's water supply may therefore lead to elevated fluoride concentrations in the Cowie River. This could have significance for domestic water use since the Cowie River is the main source of the water supply to Port Alfred. The water quality in this area has not been investigated.

3.5.9.3 Other areas

This limited assessment did not permit a comprehensive review of all possible problem areas. Such a review is required.

3.6 Managing fluoride in the environment

The responses available for dealing with elevated fluoride concentrations fall into the following broad categories:

- Do nothing
- Dilution
- Avoidance
- Resource treatment
- Supply treatment
- Source control

Appropriate choice of option is specific to each case. What follows is therefore only a broad generalised overview.

3.6.1 Do Nothing

This case most often arises by default when insidious long-term effects are not immediately apparent. Economic constraints can also come into play, whereby the exploitation of sub-optimal local resources (such as high fluoride groundwater) takes precedence over costly alternative supplies or treatment.

3.6.2 Dilution

As with total dissolved salts, in-stream dilution by catchment runoff or release from other sources can sometimes prove to be an effective and cheap option. A case in point is the Vaal River below Vaal Barrage where water released to meet downstream water requirements dilutes elevated fluoride concentrations in the effluent discharged by Sasol 1. This costs nothing to operate and is highly effective in keeping fluoride levels below the ideal guideline limits. In this instance the deliberate release of additional fresh water is not required. In other cases water has to be released to attain the desired dilution. For example, in the Vaal River system water is released from Vaal Dam to dilute Vaal Barrage to suppress undesirable salinity peaks. In this case very high benefit-cost ratios apply since the layout of the system ensures that this process loses very little water. (Excess water released during low flow conditions is trapped in Bloemhof Dam, thereby reducing the required release from the upstream dams during times of drought.) The viability of this option depends on the physical layout of the system and the cost-effective availability of a fresh water source.

3.6.3 Avoidance

This can take the form of simply switching to an alternative water source. The Gauteng salinity blending option is a more sophisticated alternative. In this case only the water actually supplied to consumers is diluted to eliminate peak concentrations, rather than dilution of the entire river flow. Again, adoption of this option is dependent on a favourable system layout and the availability of an alternative water source.

3.6.4 Resource Treatment

This is generally the most expensive and usually the least practical option. It would involve defluoridation of the entire stream to remove fluoride to attain the desired maximum limit.

3.6.5 Supply Treatment

The relationship between this option and resource treatment is roughly analogous to that between dilution and blending. It is generally much cheaper than resource treatment simply because the volume of water to be defluoridated is much smaller.

3.6.6 Source control

This option is potentially more cost-effective than supply treatment since the pollution streams tend to be more concentrated. However, this applies primarily to point sources that can be readily identified and collected.

Source control can be achieved by means of defluoridation, alternative use, reduction of intake, containment or simply cessation of the polluting activity.

3.7 Defluoridation

Options 3.6.1 to 3.6.3 should not be overlooked before resorting to defluoridation, especially when concentrations are in the acceptable range.

3.7.1 Existing Problem Areas

The map of surface water fluoride concentrations appended to this chapter indicates that defluoridation or some other action (see section 3.6) is already required in some localities. This can be due to natural conditions or development. The present investigation is not focussed on either of these cases, but rather on the impact of fluoridation.

3.7.2 After Fluoridation

Section 3.5 shows that new problem areas can emerge in downstream river systems after fluoridation is implemented. This would necessitate the adoption of one or more of the alternatives discussed in Section 3.6, some of which may involve defluoridation.

Assessment of the need for defluoridation would require the collection and analysis of a large amount of data. Site specific evaluations would also need to be undertaken to determine appropriate management options (of which defluoridation is only one alternative). It would require the establishment of some sort of trip-wire fluoride level (peak and median) above which defluoridation would be justified. The cost of defluoridation would also need to be determined to support such an investigation.

Fluoridation creates a dilemma with regard to defluoridation. For example, when fluoridation causes erstwhile acceptable conditions to become unacceptable, who will be responsible for defluoridation? (Existing dischargers, those carrying out the fluoridation or both?) Source control is directed at reducing man-made pollution inputs at source. Logically the largest and most accessible pollution sources would be prioritised for removal. In this context fluoridation would constitute the largest single source of fluoride input to the Vaal Barrage and its tributaries. It would also be the easiest to remove.

3.8 Discussion and conclusions

3.8.1 Locations of Concern

The results of this preliminary investigation indicate the need for more detailed investigations of the impact of fluoridation in the following areas:

Vaal Barrage and downstream Vaal River system: Fluoridation of the Rand Water supply would result in problematic fluoride concentrations at all eight key points examined in the Vaal Barrage catchment and the Middle Vaal River. Similar problems can be anticipated in the Bloemhof Dam, at the Kimberley and Vaal-Gamagara intakes, the Douglas Weir and down to the Vaal River confluence with the Orange River.

Upper Crocodile River: Severe fluoride problems at several points in the Upper Crocodile and Pienaars River systems are also anticipated after fluoridation by Rand Water. Since downstream river flows are highly influenced by inflows from this region, these problems could extend much further north into the Crocodile River and even the Limpopo River.

Sand River: Elevated fluoride concentrations can be anticipated in the arid Sand River downstream of Welkom and Virginia. These problems would be largely precipitated by fluoridation by Rand Water, since Sedibeng Water would require little further fluoridation at Balkfontein.

Modder River: Fluoridation is expected to give rise to problems in the Modder River upstream of and including the Krugersdrif Dam. This would lead to further problems below the dam to the Modder-Riet confluence, since the Krugersdrif Dam is the source of supply to this arid reach of the Modder River.

Waterval River: Earlier results show unacceptably high fluoride concentrations at several points in the Waterval River system. Fluoridation of the Rand Water supply would result in even higher concentrations.

Areas of low concern: The results of the preliminary analysis did not indicate undue problems in the Msunduzi, Berg and Buffalo Rivers.

Other areas: The Molopo and Cowie River systems warrant further attention. Other potential problem areas need to be identified and, where warranted, investigated.

As can be seen, four out of the five problem areas highlighted above would result from fluoridation of the Rand Water supply. This points to this as being the most critical area requiring further investigation.

3.8.2 Hydrological Variation

Much of this report was based on median analyses that did not take proper account of hydrological variation. It is essential to investigate the effect of hydrological variation. Unusually wet conditions over the last few years would also have distorted the results, leading to under-estimation of fluoride concentrations. A less biased analysis based on a longer hydrological sequence is required to give a more balanced view of the likely impact.

3.8.3 Future Time Horizons

The conclusions of this report are based on recent data. However, the fluoridation targets that are adopted need to be robust enough to account for future as well as present conditions. The impact at future time horizons needs to be considered when larger effluent discharges will make a bigger contribution to base flow. Increasing water demands will also affect the operation of river systems, further magnifying the impact of fluoridation. Constraints imposed by fluoridation targets and downstream impacts could also limit system management options. For example, in the Vaal River system the current operating system requires curtailment of the Vaal Barrage dilution option during dry periods. Downstream fluoride constraints may prevent or restrict this mode of operation forcing continued release of water from Vaal Dam. This could seriously affect system yield due to excessive wastage of water, incurring very high incremental water importation costs.

3.8.4 Storage Effects

The methodology employed in the initial analyses did not take proper account of storage effects in major dams. These important effects need to be assessed.

3.8.5 Concentration of Fluoride through Use

The simplifying assumption was made that evaporative concentration of fluoride does not occur through use. This assumption is reasonable for domestic and many smaller industrial processes. However, evaporative concentration does occur when steam is raised or water is used in cooling cycles. Kelvin, Rooiwal and Pretoria West power stations, Sappi, Iscor and Sasol would be particularly affected. High fluoride levels in the effluent discharged from certain industrial areas such as Germiston and Boksburg may also imply evaporative concentration. This would tend to increase the estimated fluoride concentrations.

3.8.6 Data Limitations

The limited nature of the investigation precluded collection of all relevant data. The impact of effluent discharged to rivers by industries was also ignored. (For example, Sappi, Sasol and Iscor all receive potable water from Rand Water. Sappi also uses effluent from Springs for process water.) This omission leads to under-estimation of the impact on downstream river systems. The latest water abstraction data, dam water balances, irrigation use, effluent flow and hydrological data needs to be collected and processed to support in-depth investigations.

3.8.7 Fluoridation Targets

The results indicate that fluoridation to an upper limit of 0.7 mg/l would result in unacceptable concentrations in several river reaches in the systems highlighted in **Section 3.6.1**. Problems may also arise in other areas that have not been examined. In such instances it will be necessary to optimise the fluoridation targets to mitigate these problems. This may also necessitate multiple points of fluoridation in some systems, which would require special attention to dosing and control systems, monitoring and safety precautions.

3.8.8 Long-term Irrigation Impacts

The preliminary analyses ignored the possible effect of fluoride on irrigation. This tends to underestimate the impact of fluoridation. The main concern is the accumulation of fluoride in some plants and the negative impact on consumers. On acid soils this could lead to enriched irrigation return flow. The accumulation of fluoride in irrigated lands could also eventually lead to negative impact on crops such as deciduous fruits. Although both of these may be long-term effects, their importance should not be ignored. In the case of Vaalharts, it took a number of decades for the salt build up in the irrigated lands to reach problematic proportions. But eventually costly remedial measures had to be implemented to drain salts from the soils (Herold and Bailey, 1996). Similar effects can be anticipated with fluoride since it is also a conservative salt. The impact of fluoride present in fertilisers should also be taken into account, in terms of both the relative importance and the cumulative effect.

3.8.9 Implementation Time Frame

The preliminary results indicate that fluoridation could have significant negative impact on large portions of the most strategic water resources of South Africa. Responsible management of these river systems requires proper evaluation of these impacts and careful selection of fluoridation targets. Adequate time is required to carry out these essential investigations. The time frame set for implementation of fluoridation is too short to allow this.

3.9 Recommendations

3.9.1 Priority Research Areas

Detailed assessments are required in the following priority areas:

- Vaal Barrage and downstream Vaal River system
- Crocodile River
- Waterval River
- Modder River
- Sand River
- Other areas yet to be identified.

3.9.2 Extension of Overview

The first step of further research should be aimed at determining which other areas warrant more detailed investigation. This should include the Molopo and Cowie River systems and other areas identified after discussions with all water boards and major water suppliers. Where applicable, preliminary evaluations should be carried out at a level similar to that described in this report. Where appropriate, short databases should be extended to firm up on the preceding estimates (e.g. see **Section 3.5.3**).

3.9.3 Optimisation of Fluoridation Targets

Fluoridation targets need to be optimised for each priority area to minimise the risk to downstream users and the natural environment.

3.9.4 System Modelling

System modelling is required to properly assess hydrological variation and to account for both present and projected future conditions. The WQT (Allen and Herold, 1988) and WRPM models offer the best means of making such assessments.

3.9.5 Supply – Effluent Quality Relationship

Water use within major supply areas should be examined and effluent fluoride data collected to determine the extent to which fluoridated water would be concentrated before discharge as effluent.

3.9.6 Long-term Irrigation Impacts

Research into the long-term accumulation of fluoride in irrigated lands, the impact on the crops grown and irrigation return flow quality is required.

3.9.7 Implementation Time Frame

The time frame for implementation of fluoridation should be revised to allow more time for the essential preparatory research to be completed for sensitive areas.

3.10 References

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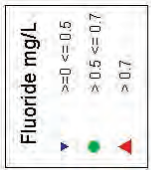
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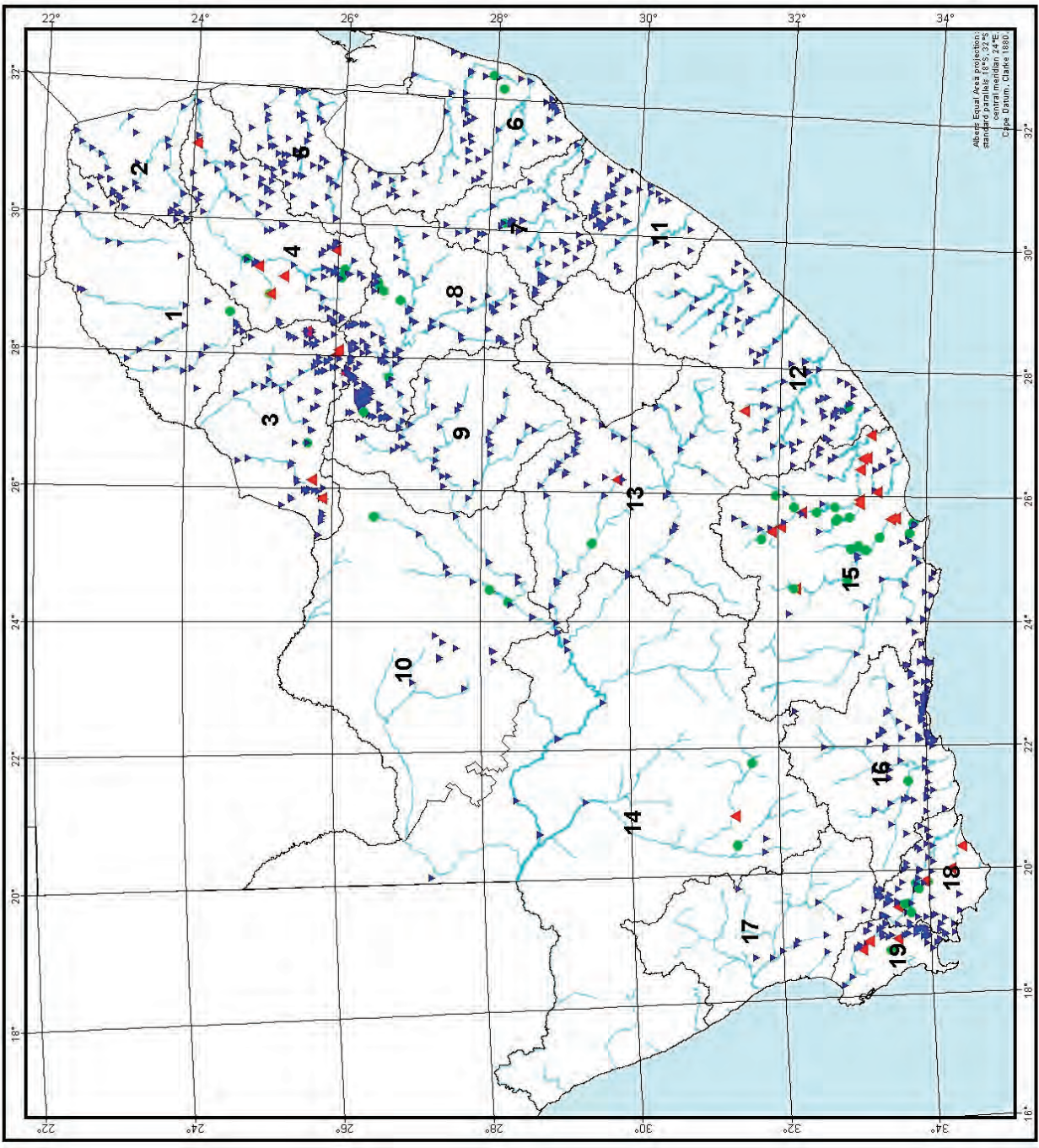


Data extracted from the Water Management System of the Department of Water Affairs and Forestry for all surface water monitoring stations (rivers, dams).

Date of extraction 2002-07-19.

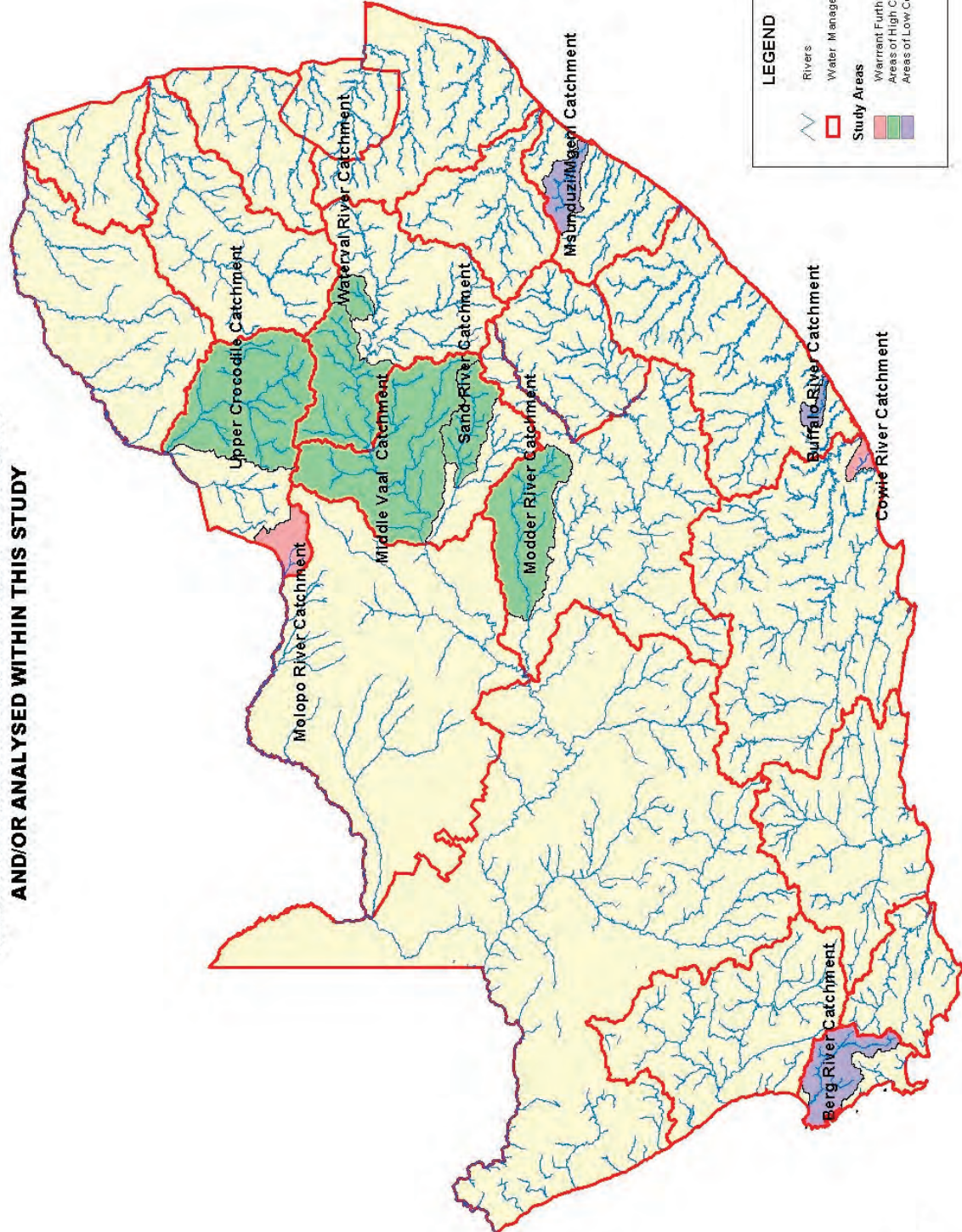
Median fluoride concentration used for all stations where more than one fluoride record exists.

- Water management Areas**
- 1: Limpopo
 - 2: Luvuvhu and Letaba
 - 3: Crocodile(West) and Marico
 - 4: Ollifants
 - 5: Inkomati
 - 6: Usutu to Mhlatuze
 - 7: Thukela
 - 8: Upper Vaal
 - 9: Middle Vaal
 - 10: Lower Vaal
 - 11: Mvoti to Umzimkulu
 - 12: Mzimyubu to Keiskamma
 - 13: Upper Orange
 - 14: Lower Orange
 - 15: Fish to Tsitsikamma
 - 16: Gourtiz
 - 17: Ollifants/Doorn
 - 18: Breede
 - 19: Berg



Albers Equal Area projection.
Standard Parallel 24°E.
Cape Datum, Clarke 1880.

**SOUTH AFRICAN CATCHMENT AREAS IDENTIFIED
AND/OR ANALYSED WITHIN THIS STUDY**



LEGEND

- Rivers
- Water Management Areas
- Study Areas
- Warrant Further Investigation
- Areas of High Concern
- Areas of Low Concern



APPENDIX 3A METHODOLOGY USED TO MAKE COARSE INITIAL ESTIMATE OF DOWNSTREAM IMPACT

INTRODUCTION

This methodology is intended to provide a rapid coarse evaluation of the fluoride concentration likely to arise in river reaches below effluent discharge points. The equations used are sound representations of the water and salt mass balance for a conservative constituent. However, time and budgetary constraints did not permit application of the mass balance to a long time series reflecting fluctuations in runoff rate and catchment fluoride export concentration. Instead a single calculation was made based on median flow conditions. Median conditions were chosen, since in most instances fluoridation would result in sub-acute conditions where the main concern is with chronic conditions, which are governed by long-term exposure.

EQUATIONS

Estimation of downstream water quality is based on a simple water and fluoride balance at each site as shown in **Figure 3A-1**.

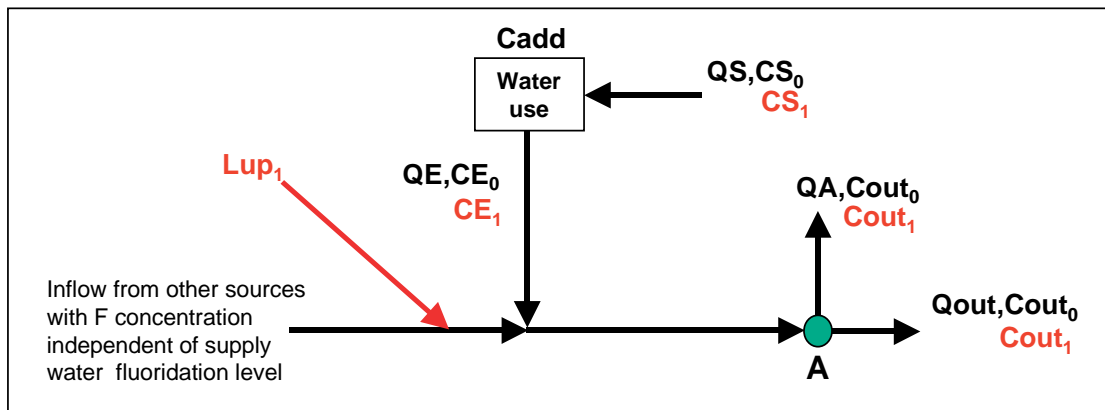


Figure 3A-1 Idealised load balance

The definitions of the symbols used in **Figure 3A-1** are described in the following equations.

The observed in-stream fluoride load at point A is calculated as:

$$L_{out_0} = Q_{out} * C_{out_0} \dots\dots\dots (1)$$

where:

- L_{out_0} = observed median fluoride load at station A
- Q_{out} = observed median average river flow at station A
- C_{out_0} = observed fluoride concentration at station A

The observed flow and load at A is the net result of all existing upstream inputs from point and diffuse sources, including the effect of sewage effluent sources at their current fluoride supply concentration, less any losses in the upstream river system.

The increase in effluent fluoride load after fluoridation is calculated as:

$$LE_{add_1} = QE * (CS_1 - CS_0) \dots\dots\dots (2)$$

where:

- LE_{add₁} = Mean increase in effluent fluoride load due to fluoridation (t)
- QE = Average effluent flow (10⁶m³)
- CS₁ = Supply water fluoride concentration after fluoridation (mg/l)
- CS₀ = Observed pre-fluoridation supply water fluoride concentration (mg/l)

The new fluoride concentration in the river at point A after fluoridation of the supply water is calculated as:

$$C_{out_1} = C_{out_0} + (LE_{add_1} + L_{up_1}) / (Q_{out} + QA) \dots\dots\dots (3)$$

where:

- C_{out₁} = Estimated new median fluoride concentration at point A (mg/l)
- L_{up₁} = Fluoride load added in upstream catchments (t)
- QA = Non evaporative water abstraction upstream of point A (10⁶m³)

The increased load from fluoridation in upstream catchments was added to account for the ripple effect of cascading use down a river system.

This methodology does not require knowledge of the present or future effluent fluoride concentrations CE₀ and CE₁ or of the change in fluoride concentration through use, C_{add}, since all that is required is the increase in load brought about by fluoridation.

Estimates of the mean effluent flow QE were obtained from local knowledge. The mean present day source water fluoride concentration CS₀ was obtained from the monthly data for the last five years, or from the local knowledge of water boards when the supply water was the aggregate of a number of supply sources. The representative fluoride concentration at the key river sampling point C_{out₀} was obtained from DWAF records for the last 5 years as was the river flow Q_{out}. For river stations Q_{out} was taken as the median flow since this more closely represents the average day by day condition (the average is too strongly influenced by short duration flood discharges). For dam stations the average is a better approximation for Q_{out} since dams trap much of the flood water, which remains in the dam to dilute long periods of base flow entering the dam. This remains an approximation since part of the flood water spills from the dam and is not available to dilute subsequent base flow runoff.

Since this methodology was applied only to calculate the median condition, it only yields a single median river concentration. This does not provide any assessment of the likely range of fluoride concentrations that will arise due to flow variation. This problem has been overcome by means of a crude approximation. The observed river fluoride record for the last 5-years was ranked to produce percentile values, including the record median. The simplifying assumption was made that the

calculated increase in the median (i.e. $C_{out_1} - C_{out_0}$) can simply be added to all the observed present day percentile values. Hence:

$$C_{p_1} = C_{p_0} + (C_{out_1} - C_{out_0}) \dots\dots\dots (4)$$

Where:

C_{p_1} = P percentile river fluoride concentration after fluoridation (mg/l)

C_{p_0} = P percentile river fluoride concentration for last 5-years (mg/l)

This is an approximation that had to be made in order to make a first order assessment of the significance.

ASSUMPTIONS

The assumptions implicit to the methodology include:

- The river fluoride concentration at the points where water is abstracted approximates that at point A.
- Evaporative concentration of fluoride between water supply and effluent discharge is negligible. This will tend to under-estimation of the impact of fluoridation.
- Fluoride in the water used consumptively is not returned to the river system.
- Fluoride in the return flow from irrigated lands can be ignored. This will lead to under-estimation of the impact of fluoridation.
- Storage elements (i.e. dams) between the points of discharge and the river monitoring station are relatively small compared to the total runoff during the 5-year period that was analysed. The validity of the assumption diminishes with increasing dam size.
- The change in fluoride concentration at all percentile values will increase by the same absolute amount as the calculated change in the median concentration.

CHAPTER FOUR

TECHNICAL AND ENGINEERING ISSUES

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4.1 Introduction

This chapter deals with the technical and engineering issues of water fluoridation, under the topics of fluoride compounds, measurement of fluoride, dosing of fluoride, administrative requirements, incident management and downstream effects. The emphasis in each of these cases will be directed towards practical, local considerations such as:

- What are the major infrastructural requirements?
- What are the major human and resource training needs?
- What are the major implicated costs?

The following sources were consulted:

- The international literature, to derive the full benefit of the many years of technical experience gathered by other countries with long water fluoridation histories.
- Two pivotal South African documents were meticulously scrutinised to expose any weaknesses or omissions, if any. They are the *Regulations on Fluoridating Water Supplies* (the *Regulations* hereinafter) which provide the legal framework for water fluoridation in South Africa, and *Water Fluoridation – A Technical Manual for Water Plant Operators* (the *Manual* hereinafter) which is a technical guidance document for South African water providers. As these documents form the backbone of the water fluoridation initiative in South Africa, their relevance and completeness are of obvious importance.
- Thirdly, a number of interviews were conducted with South African professionals in the water field. These individuals and the institutions that they represent, have all considered the practical implications of water fluoridation at length and it was deemed important to incorporate some of their experience, thinking and preferences in this document.

4.2 The source of fluoride compounds

4.2.1 The Production of Fluoridation Compounds

The Regulations allow the following fluoridation compounds, which are well-established products for water fluoridation in other parts of the world:

- Sodium fluoride (NaF), a dry, coarse, crystalline material
- Sodium fluorosilicate (Na_2SiF_6) (also known as sodium silicofluoride), a dry, fine, granular material
- Fluorosilicic acid (H_2SiF_6), a pale to straw-yellow liquid

The same three compounds are allowed in the US, while only the latter two are allowed in the UK (Department of the Environment, 1987).

The products are usually derived from two alternative raw materials; either fluorite (CaF_2 , commonly known as fluorspar) or fluoroapatite (commonly known as phosphoric rock). South Africa, incidentally, has 49% of the demonstrated fluorspar ore deposits in the world (Pelham, 1985). Fluorspar is traditionally converted to hydrogen fluoride, then to fluorine gas (F_2) and finally to C_2F_4 , which forms the foundation for Teflon based products. If the hydrogen fluoride gas in the reaction above is intercepted and reacted with silica sand (SiO_2), *fluorosilicic acid* is formed in concentrations ranging from 20 to 40%. Alternatively, the hydrogen fluoride is reacted with sodium hydroxide (NaOH) to form *sodium fluoride*. In order to produce *sodium fluorosilicate*, the fluorosilicic acid is treated with sodium hydroxide (Valkenburgh, 2002).

The other raw material is the base mineral fluoroapatite, extensively used in the phosphate fertiliser industry. Apatite rock is ground up and treated with sulphuric acid, producing phosphoric acid, calcium sulphate (CaSO_4 as a solid), hydrofluoric acid (HF as a gas) and silicon tetrafluoride (SiF_4 as a gas). The two gases are captured, scrubbed and condensed into *fluorosilicic acid* (Reeves, 1996). To produce the other two products, the process chain is the same as above.

4.2.2 Local Availability of Fluoridation Compounds

The South African fluorochemical industry is fluorspar-based. Pelchem, the main local player in this area, will probably compete in the markets for sodium fluoride and fluorosilicic acid. (Sodium fluorosilicate is expensive to manufacture due to the relatively late position in the reaction chain and also due to the relatively high cost of the sodium hydroxide that is required to manufacture it.) Pelchem has sufficient capacity to supply the South African market with its projected fluoride requirements. It has an installed hydrogen fluoride (HF) capacity of 5 000 tonnes per annum of which 3 400 tonnes per annum is currently being utilised. The available HF production capacity (1 600 tonnes per annum) translates to approximately 6 000 tonnes fluorosilicic acid per annum. It is estimated that approximately 4 200 tonnes may be required to satisfy the South African fluoridation market (Valkenburgh, 2002).

The South African fertiliser industry does not treat and refine its by-products, but discards them in waste effluents in the form of 18% fluorosilicic acid. The fluorosilicic acid from this process can also be converted to sodium fluorosilicate and sodium fluoride. It appears, however, that the local fertiliser industry is not interested in the water fluoridation market as it is too small to justify the effort involved in altering their current processes to provide the required fluoride containing compounds. Should the fertiliser industry, however, wish to enter the water fluoridation market, it should be noted that its production capacity is several times larger than the current Pelchem capability (Valkenburgh, 2002).

There is strong reason to believe that local suppliers will comfortably meet the local demand for water fluoridation chemicals. This does not preclude the possibility that some imported products may also compete, but early indications are that higher costs will prohibit their widespread use.

4.2.3 Standards for Fluoridation Compounds

The Regulations (promulgated in September 2000) state that standards for water fluoridation compounds will be specified in the Manual. Two potential problems with the Manual should be pointed out. a) It states that "imported chemicals especially should be checked for compliance with these standards". The standards should be enforced across the board, whether imported or local. b) It also lists a number of other compounds as potential water fluoridation compounds. It should be aligned with the Regulations which only allow the three compounds above (unless special application is made). These three compounds are addressed by the following standards:

- SABS EN 12173:1998 – Chemicals used for treatment of water intended for human consumption – Sodium fluoride.
- SABS EN 12174:2001 – Chemicals used for treatment of water intended for human consumption – Sodium hexafluorosilicate.
- SABS EN 12173:1998 – Chemicals used for treatment of water intended for human consumption – Hexafluorosilicic acid.

4.2.4 Compliance of Local Fluoridation Compounds

Detailed chemical analyses for fluorosilicic acid and sodium fluorosilicate were obtained from Pelchem (Valkenburgh, 2002). (Analyses for sodium fluoride were not available.) The Pelchem results indicate that both fluorosilicic acid and sodium fluorosilicate conform to the required SABS standards.

Pelchem also provided the results of heavy metal analyses that were performed on fluorosilicic acid produced in batches on laboratory scale using production reagents. A total of 11 batches were produced. Triplicate heavy metal analyses were performed on every batch and the combined data set for every metal was analysed to deliver the upper limit of a 99% confidence interval for each heavy metal evaluated. The heavy metal content values derived from this experimental production indicated values that fell within the allowable SABS limits. According to Valkenburgh (2003) this would indicate that 99% of all periodically drawn production samples would demonstrate heavy metal contents below this limit. The sketchy information in this paragraph obviously does not guarantee compliance, but is quoted to show that no serious quality problems have been identified at this early stage. This, of course, will have to be borne out by the regular testing called for once water fluoridation starts.

Preliminary results indicate that locally produced fluoridation compounds will comply with the SABS standards, which are the same as those of the European Union.

4.2.5 The Choice of Fluoridation Compound

A recent survey of 1280 water fluoridation plants in the US showed that 76% of the plants use fluorosilicic acid, 12% use sodium fluoride, 11% use sodium fluorosilicate and the remaining 1% of the plants a combination of the above. Amongst the large plants (arbitrarily defined having a treatment capacity of more than about 4 Ml/d), the corresponding percentages were 72%, 21%, 5% and 2% (Lalumandier *et al*, 2001). A recent publication places the business manager of a large US marketer of fluoride compounds on record as anticipating an ongoing trend from the granular compounds to the easier-to-handle fluorosilicic acid (McCoy, 2001). Fluorosilicic acid therefore has the lion's share of the market in the US and it appears to be growing.

A survey of major South African water treatment institutions (Rand Water, City of Cape Town and Port Elizabeth) has also indicated a preference for fluorosilicic acid. Some of the motivations provided for this choice are:

economy at larger water treatment works,
ease of use,
no dust control problems and
commercial availability.

4.3 Delivery, handling and storage of fluoridation compounds

4.3.1 Road Safety

South Africa has extensive legislation dealing with the transportation of hazardous chemicals on public roads, which complies with the United Nations recommendations on the movement of dangerous goods. The legislation deals comprehensively with matters such as registration of all operators transporting dangerous goods, special category driving licenses, minimum entry age of 25 years for new drivers, vehicle signage, documentation to be carried with each load, a special inspectorate to screen dangerous routes and to audit the premises of operators, consignors and consignees, mandatory insurance, accident reporting, etc.

The quantity of material that may be transported before specific compliance with the road safety legislation is required is stated in the table below. The quantities are prescribed by SABS 0230:1997 which in turn determines the limits after consideration of the nature of the material (risk grouping) and the packaging (packaging grouping) that the material will be transported in. Each chemical to be transported is assigned a risk weighting that is added to other risk weightings in the same transport load. Once a threshold is exceeded, compliance with the law is required. The limits stated below refer to the transport of only one fluoride-containing compound at a time.

Table 4-1. Load size limits before compliance to the Road Traffic Act is required according to SABS 0230:1997

Chemical	Risk Group	Packaging Group	Load limits
Sodium fluoride	Class VI – Toxic/infectious	Group II	50 kg
Sodium fluorosilicate	Class IV – Toxic/infectious	Group III	500 kg
Fluorosilicic acid (40%)	Class VIII - Corrosive	Group II	200 kg

As fluorosilicic acid (a liquid) seems to be the likely chemical for the initial implementation of water fluoridation, the probable means of transportation from the Pelchem production facility will be one or two dedicated bulk road tankers (Valkenburgh, 2002). This means of supply is adequately covered by existing legislation on road traffic. Smaller consignments of the acid will be transported in drums. Both transport formats are covered under the legislation and standards quoted above. Other specifications that apply to the transport of the fluoride containing chemicals are:

- SABS 0228:1995 – Code of Practice for the Identification and Classification of Dangerous Goods and Substances, and
- SABS 0229:1996 – Code of Practice for Packaging of Dangerous Goods for Road and Rail Transport.

4.3.2 Delivery and Storage of Fluoridation Compounds

The Road Traffic Act makes provision for the appointment of a qualified person to supervise loading and off-loading of the chemicals. In other words, the onus for the responsible handling of the chemical during off-loading is still on the road transport operator.

The facilities provided at the treatment plant, and the standard operational procedures are all subject to the Occupational Health and Safety Act (Act 85 of 1993), more specifically the “Regulations for Hazardous Chemical Substances” - Regulations made under the OHS Act, 1993 (GN 1179, 25 August 1995). The Department of Health Regulations on fluoridation essentially state that:

- Unauthorised persons should not be allowed access to the storage site
- Unforeseen spillage of the fluoride compound may not contaminate the environment
- Unforeseen spillage of the fluoride compound may not cause injury
- There must be a comprehensive operational programme, safety measures and emergency procedures regarding the storage and handling of fluoride compounds at the fluoridation plant.

The OHS regulations on HCS (Hazardous chemical substances) are more stringent than the Department of Health regulations and will therefore effectively control the procedures pertaining to the handling of fluoride on site. The OHS regulations deal with the following issues in great detail:

- Information and training issues
- Responsibilities of owners, operators and workers
- Monitoring and surveillance
- Record keeping
- Protective gear, equipment and facilities, and
- Disposal of chemicals.

The Manual also contains more detailed guidelines on the storage of the various fluoride compounds than the Regulations. These guidelines are general in nature and correspond to good practice for the storage of all water treatment chemicals. In summary, they stipulate that:

- The chemicals should be secure
- Dry chemicals should be kept dry and should not be stacked too high
- Any spillage of the chemical must be contained in the storage area
- The storage area must have infrastructure in place to deal with spillages, i.e. water supply, piping and valves for controlled drainage, sufficient ventilation
- The chemical should not be stored in the vicinity of corrodible materials and instruments
- Dust should be minimised when dealing with dry chemicals
- The containers used to ship and store the chemicals should be cleaned and disposed of in a responsible manner.

The transport of fluoride will probably be by road tanker and the safety and handling aspects are comprehensively covered by current legislation.

4.4 The dosing of water with fluoride

4.4.1 Different Dosing Systems

For each of the three permissible fluoridation compounds, a specific type of dosing system is required:

- For sodium fluorosilicate, a *dry feeder* is required which transfers the dry compound at an adjustable volumetric rate to a split-stream of the water to be treated.

- For fluorosilicic acid, a *metered pumping* system is required which transfers the liquid at an adjustable volumetric rate to a split-stream of the water to be treated.
- For sodium fluoride, a *saturator* system is required which delivers a solution with a constant saturation concentration of fluoride.

The initial choice of the fluoride compound to be used therefore predetermines the type of dosing system and the hardware associated with the fluoridation plant. The details of these time-tried systems are covered in the Manual and are not repeated here. All three systems deliver a concentrated solution of fluoride to a day-tank, which holds no more than one day's supply. From this tank, the solution is delivered in a controlled, even way to a dosing point which should ensure rapid, complete dispersal of the solution into the main body of water.

4.4.2 Design of Dosing Systems

There are no laws, regulations, or requirements governing the design or installation of fluoridation plants. In this sense, fluoridation is no different from any other treatment chemical at South African water treatment plants. The Manual does, however, include a number of guidelines to assist designers of such systems. There are a number of smaller inconsistencies between different parts of the Manual, e.g. those sections dealing with maximum flow rates through saturators, minimum feed water pressure and threshold hardness before feed water should be softened.

A number of important safety features are integral to the design of a fluoridation plant, which are all appropriately and adequately covered in the Manual:

- *Vacuum breakers or air break devices* are used to provide a break in the make-up water feed line to prevent back-siphonage of saturated or unsaturated solutions into the water supply system.
- *Anti-siphon valves* are installed in the feed line between the metering pump and the dosing point to prevent the siphonage of larger than intended flows of fluoride into the process stream.
- *Day tanks* are used to minimize the risk of dumping large volumes of make-up chemicals into the process stream, as it will contain a maximum of two day's supply of make-up chemicals. In most cases it will only contain the volume needed for a single shift.
- *Solution tank mixers* are used to ensure the solution of sodium fluorosilicates in solution tanks.
- *Alarms* are used to alert operators as to a number of conditions that may lead to underfeed or overfeed situations such as diminished fluoride compound levels, diminished feed or make-up water flow, etc.
- *Flow restrictors* are installed to prevent overfeeding of the make-up water supply to saturator systems.
- Transfer of fluoride solutions should be done by pumping and not by siphoning or gravity flow.

As with all dosing systems, the importance of the correct and appropriate selection of quality hardware is self-evident. A single example from the literature will illustrate the domino effect of a single component malfunctioning (Anonymous, 1994). A magnetic flow meter was installed in the fluoride feed line with a small flow restrictor. This caused the restrictor to clog, and the corrosion of the electrodes of the flow meter. As the flow meter output decreased, the automated dosing pump increased its flow, eventually leading to an overdose of 16 Ml of water, which had to be drained from a reservoir.

A final design consideration is the *position* of the dosing point. The ideal place for the addition of the fluoride solution or suspension is in the line between the sand filters and the clearwell. Where a large stream of raw

water (such as at Rand Water at Zuikerbosch) is treated in multiple treatment plants, it is conceptually simpler to have a single fluoride dosing point. Such practical considerations also need to take into account whether the position of the dosing point will not lead to undesired chemical effects – a point returned to in a later section.

4.4.3 Operation and Maintenance of Dosing Systems

The Regulations require that operational, safety and emergency programmes are in place for the entire fluoridation scheme and that these programmes are made available to all personnel that may be involved in any way with fluoridation. No guidelines are provided for the format or level of detail of these programmes.

The Manual emphasises the importance of a preventative maintenance programme for the fluoridation plant. Some general guidelines are given, but this will have to be specified in much more detail for each specific plant to include the recommendations of individual component suppliers.

To date none of the larger water treatment institutions contacted in a limited survey have developed the required guidelines and procedures (De Leeuw, 2003; Mia, 2003; Lourens, 2003). The main reasons stated for this was the lack of guidance regarding the scope, content and formulation of these documents as well as the fact that none of the fluoridation programmes have come close enough to implementation to warrant the development of these documents.

Despite the emphasis placed on a comprehensive set of guidelines and procedures for each fluoridation installation, there is a lack of guidance regarding the scope, contents and formulation of these documents. No water providers have to date completed this documentation requirement.

4.5 The measurement of fluoride in water

4.5.1 Measurement Options

The Regulations leave a choice between *continuous monitoring* (with calibration once every 24 hours) and *grab sampling and analysis* (to be performed every shift). The Manual adds the specification of either the *ion-selective electrode* method or the *SPADNS colorimetric* method for the measurement of fluoride.

The Centers for Disease Control in the US, in contrast, recommends that the fluoride concentration is measured once a day (Pontius, 1991). In the US, less than 1% of water fluoridation plants make use of continuous monitoring systems (Reeves, 1996). In the UK, a continuous recording fluoride monitor is required on the final water for all new installations, calibrated automatically every 24 hours. For raw water and distribution system sampling, a specific fluoride ion electrode is required (Department of the Environment, 1987).

The ion-selective electrode measures the fluoride potentiometrically by using a fluoride electrode in conjunction with a standard single junction sleeve-type reference electrode and a pH meter. Fluoride ion activity depends on the solution total ionic strength and pH, and on fluoride complex species. Adding an appropriate buffer provides a nearly uniform ionic strength background, adjusts the pH, and breaks up complexes so that the electrode measures concentration. In general, the measurement range of fluoride by this method is 0,1–100mg/l. The sample pH should be between 5 and 9; extremes of pH interfere as the fluoride forms complexes with several polyvalent cations such as Si^{4+} , Fe^{3+} and Al^{3+} . The degree of interference depends on the concentration of complexing cations, the concentration of fluoride and complex species. The addition of pH 5,0 buffer containing a strong chelating agent preferentially complexes

aluminium (the most common interference), silicon and iron, and eliminates the pH problem. The equipment cost for this method is fairly high, while the chemical consumption, which represents the main running cost, is low. (WHO Monograph, 2002)

In the SPADNS colorimetric method, the sample is treated with SPADNS reagent following distillation to remove interferences. The fluoride reacts with the dye, dissociating a proportion into a colourless complex anion (ZrF_6^{2-}); and the dye. As the amount of fluoride increases, the colour produced becomes progressively lighter and measured colorimetrically at 570 nm in a spectrophotometer or at 550 to 580 nm in a filter photometer. The method covers the range from 0,1 mg/l to about 1,4 mg/l. The SPADNS reagent is more tolerant of interfering materials than other accepted fluoride reagents. The addition of the highly coloured SPADNS reagent must be done with utmost accuracy because the fluoride concentration is measured as a difference of absorbance in the blank and the sample. A small error in reagent addition is the most prominent source of error in this test. The capital cost for the spectrophotometer or photometer is high, but chemical consumption, which represents the main running cost, is low. (WHO Monograph, 2002)

The summaries in the previous two paragraphs are provided to make the point that both options require fairly elaborate equipment and materials, and especially a high degree of operator skill, experience and diligence. The consistent, accurate measurement of the fluoride concentration in water is pivotal to accurate dosage and control and should remain a high priority for water providers.

4.5.2 Quantitative Estimation of Measurement Error

It is clear that accurate fluoride measurement is a pivotal requirement of successful fluoridation, but that it is, at the same time, not a trivial requirement to comply with. In an attempt to assess the potential significance of this issue, some research was conducted specifically for this study (Haarhoff, 2003) which is briefly summarised here. A wide search was conducted for data where different laboratories measured the fluoride concentration of the same water by split water samples. Three sources of such data were found:

- The South African Bureau of Standards runs an ongoing programme called SABS Watercheck, which sends monthly sets of samples to approximately 50 to 70 analytical laboratories in South Africa. Fluoride is included as a determinant every third month. This programme has been operating for about five years. The raw data from the most recent four sampling runs (thus covering the calendar year 2002) were obtained, covering 12 samples, with 631 reported concentrations from 55 different laboratories. Both natural and synthetic samples were included.
- The Division of Water Technology (DWT) of the CSIR ran an inter-laboratory comparison programme from the middle of the 1970's to 1998. A wide variety of sample types and analytical methods were covered for water, sewage, sediment and sludges. During this programme, samples for fluoride analysis were distributed on eight occasions, comprising of both synthetic (made up from distilled water with reagent-grade chemicals) and natural samples. In total, 21 samples were sent out between 1977 and 1998, with an average of 35 laboratories participating in each survey. A total of 725 data points were thus collected.
- Medunsa conducted a small survey during 2002. Five samples of tap water, spiked in varying degrees with fluoride compounds, were sent to 10 commercial laboratories in the Gauteng area for fluoride analysis, with a clear note that it formed part of an inter-laboratory comparison.

After data capture and the application of some mild exclusion criteria, a total of 1315 data points, covering 36 samples over 25 years, were available for statistical analysis. The following were the main findings:

- There were no significant differences in accuracy amongst the different analytical methods.
- The variability of the measurements was significantly less for synthetic samples than for natural samples, presumably due to lack of interfering substances.
- There were no significant differences in accuracy between the instrumentation currently used in South African laboratories and the instrumentation used ten years ago or more.
- For the natural samples, a conservative error band between –39% and +17% was found.

If this is indeed the best measurement accuracy that can be attained at water fluoridation plants, the consequences would be serious, as will be shown in the next section.

Fluoride measurement in natural water samples is not as accurate as generally assumed. A preliminary estimate of the expected error band ranges between –39% and +17% of the true value.

4.6 Dosage control

4.6.1 Legal Requirements

The Regulations are elaborate and specific on the required dosing accuracy. The major requirements can be summarised as follows:

- The acceptable instantaneous operational variation is 0,2 mg/l around the optimum level of 0,7 mg/l – about 28%. The fluoridation installation must operate between these levels for at least 90% of the time.
- Alarms should be triggered if fluoride is dosed at levels of 1 mg/l above the optimum fluoride concentration, i.e. at 1,7 mg/l or more.
- The average monthly fluoride concentration must not deviate by more than 0,1 mg/l around the optimum level of 0,7 mg/l.

These requirements are relatively strict and are approximately the same as in the UK (Department of the Environment, 1987). The US Public Health Service recommends to individual states that the control range should be between 0,1 mg/l below to 0,5 mg/l above the optimal level. The recommendations are generally followed by the individual states with some state stricter (e.g. Illinois tolerates a control range of 0,9 – 1,2 mg/l for its optimal level of 1,0 mg/l) and some states more lenient (e.g. Maine a range of 1,0 – 2,0 mg/l for its optimal level of 1,2 mg/l) (Lalumandier *et al*, 2001).

4.6.2 Quality Control Measures

The Regulations recognise the difficulty of continuously meeting these requirements. They therefore also call for three feedback loops to allow for correction to the dosage rate if something should go wrong:

- The first feedback loop is an immediate one that measures the fluoride concentration immediately after fluoridation, either continuously, or once per shift. Should these values show a drift from the optimum towards higher or lower concentrations, adjustments can be made. The weakness in this feedback loop is that the measurement of fluoride concentration is also implicated as a potential source of error, as will be demonstrated shortly.
- The second feedback loop has a lag time of one month, as the monthly average actual fluoride dosage must be within 0,1 mg/l. If this monthly control is done on the basis of the change in fluoride inventory and the total water volume fluoridated, it will only partially eliminate the

problem outlined in the previous bullet. This method is only a check on the fluoride *added* to the water, and not compliance with the target value. If the monthly average fluoride concentration is derived from mere averaging of measured values, it will not guard against instrument errors at all.

- The third feedback loop is more indirect, as it calls for weekly sampling in the distribution system. This loop has a lag time of one week, and suffers from the same weakness as above, namely that it will not detect a systematic build-up of a fluoride measurement error.

4.6.3 The Effect of Fluoride Measurement Error

To dose the correct amount of fluoride into water, the fluoridation plant operator has to a) measure the fluoride concentration in the raw water, b) measure the water flow rate, c) calculate the fluoride dosing rate to make up the shortfall towards the target concentration and d) check the procedure by measuring the fluoride concentration in the fluoridated water. For the purposes of this section, assume that there are no calculation errors, that the water flow and the fluoride solution in the day tank are exactly known, and that the fluoride dosing pump can be set with absolute accuracy. The only error to consider is therefore the error due to the measurement of the fluoride concentration before and after dosing.

It is obvious that any measurement error will be compounded during the immediate feedback loop. This is illustrated by the following example, where a constant under-measurement error of 30% is assumed for illustration:

- The raw water fluoride concentration is actually 0,20 mg/l, but measured as 0,14 mg/l. The shortfall is therefore actually 0,50 mg/l below the target level of 0,70 mg/l, but perceived by the operator to be 0,56 mg/l.
- The dosing pump is set to add 0,56 mg/l, resulting in an actual concentration of 0,76 mg/l or 0,06 mg/l above the target. The operator measures this as 0,53 mg/l and still perceives a shortfall of 0,17 mg/l.
- The operator, correctly, increases the dosing rate by 0,17 mg/l to get an actual concentration of 0,93 mg/l, which is still perceived as 0,65 mg/l or 0,05 mg/l short of the target.
- This cycle continues until the concentration stabilizes at the perceived target concentration. By this time, the actual concentration is about 1,00 mg/l, or about a 40% overdose. While this may not be serious from a health perspective, it certainly is unacceptable in terms of the specified dosing control tolerances.

The periodic inventory check appears to be an independent check on the dosing accuracy. The fluoridation operator should check this requirement by a careful site inventory of on-site fluoridation chemicals and the volume of water fluoridated since the previous check. An inventory check will indeed provide an external check on how much fluoride was *dosed*. To then obtain the average concentration in the fluoridated water, the fluoride *dosed* has to be added to the concentration *originally present*, which can be obtained in no other way than taking the volume-weighted average of the raw water concentrations measured during the week. It is clear that an inventory check is therefore also dependent on the accuracy of measuring the fluoride concentration in the raw water. Using the same example as above where the raw water concentration is undermeasured by 0,06 mg/l, the target will therefore also be missed by 0,06 mg/l without knowing.

4.6.4 Dosing Accuracy Reported by Others

The earlier South African Commission of Enquiry into water fluoridation (Staatsdrukker, 1967) declared unequivocally that fluoride can be added safely to water and that the concentration can be maintained at the desired level. This conviction was based on submissions made by the Chief Engineer (Rand Water) and a Chief Research Officer of the National Institute of Water Research (CSIR).

The only systematic study of fluoride dosing error known to the authors has recently been published (Lalumandier *et al*, 2001). Operators at 1280 fluoridation plants in 12 US states responded, amongst others, to a question of how close they could maintain the fluoride dosing level to the optimal level. Only 25,9% responded that they could maintain it within 0,1 mg/l of the optimal level (in other words, between 0,6 mg/l and 0,8 mg/l if the target is 0,7 mg/l); another 49,3% could maintain it between 0,1 and 0,2 mg/l from the optimal level; 19,5% could stay between 0,2 to 0,3 mg/l of the optimal level; 4,5% could not stay within 0,3 mg/l of the optimal level. For the large plants (above a capacity of about 4 Ml/d) the performance was significantly better, with 33,5% of the large plants maintaining the dosage within 0,1 mg/l of the optimal, as opposed to 21,3% for the small plants. The two main causes for the dosing error were reported to be problems with feeding equipment (18,4%) and variations in raw water flow (12,8%). Poor operator training of operators was blamed for the dosing error in 8,7% of the responses.

It is clear, from the US study quoted above, that the dosing control range as legislated in South Africa will not be met without a serious effort. Current US practice suggests that only 75% of US plants will meet the instantaneous target of the SA legislation, and only 26% the monthly target. It should be added that it is not clear against what the US operators have measured their dosing performance. If they compared their dosing accuracy against their own site measurements, it means that the potentially significant measurement error has not been included in the compliance reported in the US study.

Cape Town and Port Elizabeth have indicated that they anticipate some difficulty in maintaining the prescribed dosage limits because they were considered to be too strict and probably at the limits of monitoring accuracy. The legislated limits have a direct effect on the cost of monitoring and control (De Leeuw, 2003; Geldenhuys, 2002; Lourens, 2003), and could add significantly to the overall fluoridation cost.

Only one example of an overdosing event will be quoted to illustrate its damaging consequences. In 1993 there was an equipment failure in the town of Middleton, Maryland, which caused overdosing of fluoride. As a result, the entire supply system had to be drained, its customers supplied with bottled water, and fluoridation permanently discontinued. The nearby small town of Poolesville, Maryland, used this example (to illustrate the difficulty of accurately controlling the dosage) in a fact sheet posted on the Internet for its current water customers (Town of Poolesville, 1996).

In a rare example of a Public Health Risk Management Plan specifically directed towards the overdosage of fluoride (Ministry of Health, New Zealand, 2001), seven independent potential causes for fluoride overdosage are identified:

- Dosing solution at the wrong concentration
- Back-siphoning from day tank
- Malfunctioning dosing apparatus
- Dosing rate set incorrectly
- Dose controller malfunctioning (if automatic system is used)
- Samples not taken, or incorrectly recorded
- Monitoring method incorrect.

This management plan considers the following to be the most important preventive measures:

- Regularly check dosing solution
- Provide high-level alarm
- Regularly check monitoring accuracy, with split samples to external laboratory
- Proper training of treatment plant staff

The dosing tolerances of fluoride are strict and will not be met without a serious effort by water providers. One of the principal reasons is the inherent inaccuracy of fluoride measurement in natural water samples due to interferences.

4.7 Interaction of fluoride with drinking water

A number of chemical reactions are ascribed to the “artificial” or “added” fluoride due to water fluoridation. Two remarks are made as an introduction to this section. It should firstly be noted that fluoride added to water is effectively 100% dissociated. There is absolutely no difference between “added” dissociated fluoride and “natural” dissociated fluoride in terms of chemistry and bio-availability (Jackson *et al*, 2002). A very small fraction of the fluoridation compound does not dissociate and this fraction is often implicated as harmful. The case in point is the dissociation of fluorosilicic acid that could give rise to the formation of undissociated species such as $\text{SiF}_2(\text{OH})_4^{2-}$. This problem has not been researched properly and is a cause for concern. It should be noted, however, that limits on these substances have not been published by any of the regulating authorities internationally. Secondly, fluorine chemistry is long studied and well understood and most of the claims can be rationally analysed in terms of dissociation constants, solubility products and other principles of equilibrium chemistry (Peng *et al*, 1996; Jackson *et al*, 2002).

4.7.1 Fluoride Reaction During Treatment

The first potential problem following the addition of fluoride to water is the formation of non-soluble precipitates with calcium and magnesium, especially at elevated pH values. This could cause a problem in South African plants where lime stabilisation is used. The Manual therefore recommends that the fluoride and lime dosing points be separated as far as possible. Rand Water, who uses a high-lime process, has recently demonstrated this by simulating their treatment process at bench scale. If fluoride were to be dosed at the entrance to the plant (a convenient option as this affords a single dosing point as opposed to multiple dosing points at different positions on the plant), 20% of the fluoride would precipitate in the subsequent settling step due to the formation of non-soluble compounds. Rand Water has therefore confirmed that the optimal fluoride dosing point should be after treatment, alongside the dosing point of final chlorine (Geldenhuis, 2002).

The second potential problem is the formation of strong complexes between fluoride and aluminium (Harvey *et al*, 2002). At pH6, for example, the calculated solubility of aluminium in the presence of solid aluminium hydroxide flocs is 0.083 mg/l. If 1 mg/l of fluoride is added, the calculated solubility of aluminium increases to 0.649 mg/l – a dramatic increase. Fortunately, this effect drops off rapidly at pH7, and is negligible at pH 8 and pH9. The Manual therefore cautions against a fluoride “loss” of up to 30% in the presence of aluminium.

The increased aluminium due to the increased solubility levels may in itself present some problems. Many of the raw water sources in the Western Cape are classified as soft, corroding waters that contain elevated levels of humic substances. To manage the high levels of colour (humic substances) in the water, aluminium sulphate or sodium aluminate is used as treatment chemicals. Many of these plants already have elevated

levels of aluminium in their raw water. With the addition of additional aluminium, these plants find it difficult to maintain the Class I levels for aluminium required by SABS 0241. This problem will be exacerbated by the addition of fluoride (Pieterse, 2003).

There are South African scenarios where the aluminium problem should be carefully considered. One scenario is where high doses of aluminium are used as coagulant. (This potential problem has been eliminated at many plants who have switched in recent decades from aluminium compounds in favour of ferric chloride or polymers as their principal coagulant.) Another scenario is where treatment takes place at a naturally low pH. This is a problem currently investigated by the Cape Town Metro, which experiences a combination of low pH and high aluminium concentrations (Pieterse, 2002).

4.7.2 Fluoride Reaction in the Distribution System

Within the distribution system, the concerns are essentially the same as in the treatment plant. One concern is the precipitation of calcium fluoride (which will form an unwanted deposit as well as reducing the effective fluoride concentration). Another concern relates to aluminium deposits which may have formed over many years before water fluoridation. When fluoridation is implemented, these aluminium deposits could be dissolved to cause an unacceptably high aluminium concentration.

4.7.3 Fluoride Effects on Downstream Users

A claim is frequently made that fluoridation will lead to more corrosion of downstream fittings and appliances. It is true that the addition of a fluoride compound will increase the conductivity of the water, and that the addition of specifically fluorosilicic acid will depress the pH. Both these factors will very slightly increase the corrosivity of the water if left unchecked. But the adjustment of the final pH to obtain the desired degree of water stability is already part and parcel of water treatment plant operation – a step normally attained by lime addition (if acidic coagulants are used) or by carbon dioxide addition (if coagulation is done at alkaline conditions). In other words, only very slightly more lime or less carbon dioxide is needed to obtain exactly the same degree of stability. The allegation that water fluoridation will cause corrosion of water delivery systems can therefore not be supported.

A common concern is that high fluoride concentrations may be harmful in certain industries, particularly those involved in the production of food, beverages, pharmaceuticals and medical items (Geldenhuys, 2002). If the addition of fluoride to potable water is indeed a problem, industry has not been vocal about it. Lubout (2003), Manager of Water Quality Marketing of Rand Water, states that Rand Water has not encountered strong opposition from industry to fluoridation, but that questions and concerns have been raised by the mining industry regarding the high water consumption level of miners and how the fluoridation would impact on them, as well as the potential corrosive effect of fluoride.

Other concerns relate to industries that make use of yeast in their processes. Prof Axcell of SAB (2003) however states that he has investigated the impact of fluoridation of water supplies on their industry and although he would prefer not to have to deal with the fluoride, he does not expect it to have a marked impact on the brewing process. Professor Axcell states that he has confirmed this internationally with brewers that have been working with fluoridated water for many years now. On the issue of corrosion Prof Axcell states that they do experience problems with the pitting of stainless steel vessels due to chloride in the water. The amount of fluoride that will be present in the water after fluoridation will however be negligible compared to the chloride levels and he therefore does not expect any additional problems.

No specific downstream user group could be identified which will be adversely affected by water fluoridation at the levels proposed.

4.8 Routine documentation

In terms of the Regulations, a water provider has to record the following items at weekly (or shorter) intervals:

- Volume of water treated
- Average raw fluoride concentration in raw water
- Total fluoride consumption
- Average fluoride concentration added to fluoridated water (calculated from the above)
- Highest fluoride concentration in fluoridated water
- Lowest fluoride concentration in fluoridated water
- Description of interruptions and failures, their causes, how they were rectified and how they will be avoided.

These weekly records must be available for public inspection for a period of ten years and must also be submitted to the local health authority.

At monthly intervals, the water provider must summarise the routine data from the weekly reports and submit it to the local health authority. A second report, dealing with mishaps and how they were addressed, has to accompany the routine report.

This is the end of the responsibility of the water provider. The local authority, however, is charged with the following additional responsibilities:

- Interim submission of any of the weekly or monthly reports to the Department of Health if deemed necessary.
- Submission of the monthly reports to the MEC for Health of the responsible provincial government, every three months
- Submission of the monthly reports to the Director-General of the national Department of Health, annually
- Submission of the monthly reports to the Director-General of the Department of Water Affairs and Forestry, annually.

For routine operation, the administrative requirements seem to be comprehensively defined in the Regulations, with the following comments:

- There are some discrepancies in the Regulations, for example where average monthly values have to be entered into a weekly report.
- The format and level of detail in the reports are undefined. It would streamline national reporting on fluoridation if the format of the reports could be standardised.
- No deadlines are stipulated before reports have to be submitted.

The Manual provides further guidelines for internal administration, which is nothing but the normal practice of good housekeeping:

- Complete data on the maintenance of the fluoridation equipment including programming for preventative maintenance.
- Calibration curves
- Information on spare parts and vendors

It seems necessary to develop a more detailed framework for networking, reporting and quality control amongst those water providers that fluoridate. A good example is a comprehensive set of guidelines developed during two advisory workshops held in the USA under the auspices of the Centers of Disease Control (CDC) in 1993, aimed at reviewing and revising the CDC's fluoridation recommendations, which was eventually published (CDC, 1995). An example of such a detailed form can be found on the Internet (Florida Department of Environmental Protection, 1996).

The US is developing a Fluoridation Reporting System (FRS) at two levels. At the first, plant data is entered into a state-wide database and plant reports are generated via an Internet connection. At the second level, the database can be exported elsewhere via high speed data transmission methods. To encourage this development, an amount of about R2m was available to assist water providers with this implementation (CDC, 1999).

Although the reporting procedures and the reporting chain have been explicitly defined in the Regulations, the format and medium of reporting are undefined, which will complicate the analysis and synthesis of fluoridation reports at a provincial and national level.

4.9 Incident management

4.9.1 Specific Actions

The Regulations distinguish between three types of incidents:

- Where the average fluoride concentration over a 24h period is between 1,7 and 10 mg/l, the matter must be recorded and immediately reported to the local health authority.
- Where the fluoride concentration exceeds 10 mg/l (the Regulations do not state whether this is a instantaneous value or also averaged over a 24h period), the water provider must immediately inform the local health authority, the water users, the Director-General Health and the Director-General Water Affairs and Forestry.
- A major spill (undefined), which must be treated as a >10 mg/l incident.

The Manual provides more detailed guidance of how fluoride overfeed should be practically corrected, in a table reproduced below.

Table 4-2. Recommended actions for fluoride overfeed (from Manual)

Fluoride content	Perform the following actions:
0.5 above optimum to 2.0	<ul style="list-style-type: none"> • Leave the fluoridation system on. • Determine what has malfunctioned and repair it
2.0 to 4.0	<ul style="list-style-type: none"> • Leave the fluoridation system on. • Determine what has malfunctioned and repair it • Notify your supervisor and report the incident to the appropriate local authority.
4.0 to 10.0	<ul style="list-style-type: none"> • Determine what has malfunctioned and immediately try to repair it. • If the problem is not found and corrected quickly, turn off the fluoridation system. • Notify your supervisor and report the incident to the appropriate local authority. • Take water samples at several points in the distribution system and test the fluoride content (save the part of the water sample not used). • Determine what has malfunctioned and repair it. Then, with the supervisor's permission, restart the fluoridation system.
10.0 or higher	<ul style="list-style-type: none"> • Turn off the fluoridation system immediately. • Notify the supervisor and report the incident immediately to the appropriate local authority and follow their instructions. • Take water samples at several points in the distribution system, and test the fluoride content. Save part of the sample for the lab to test. • Determine what has malfunctioned and repair it. Then, with the supervisor's permission, restart the fluoridation system.

The US Regulations has set a maximum contaminant level (MCL) of 4.0 mg/l for fluoride. Should this be exceeded, the state has to be notified within seven days and three follow-up samples at the same point should be taken within one month. Compliance is based on the average of the four analyses. Major spills are considered to be larger than 450 kg of sodium fluoride and must be reported nationally (Pontius, 1991).

4.9.2 Operational / emergency programme

The Regulations place heavy emphasis on having a comprehensive programme dealing with operation, inspection, servicing, maintenance, fluoride measurement, spills, handling and emergency response. This programme must be in writing and available to all involved personnel at all times. Training must ensure that all involved are fully informed with regard to their duties, responsibilities and tasks. Moreover, these procedures cannot be developed gradually as fluoridation is implemented, but the programme should be planned and detailed ahead of time; it has to be submitted as part of the application to fluoridate.

Despite the obvious importance of such a programme, no guidance is given on how, and to what level of detail such a programme should be developed. The development of such a comprehensive plan by each water provider is a costly exercise, and it is very unlikely, in the absence of guidelines, that any two programmes will cover exactly the same ground.

There is a need for a generic blueprint programme which meets the quality control requirements of the Departments of Health and Water Affairs, which can then be relatively quickly and easily amplified and adapted to the specific needs of each water provider.

4.10 Human resource requirements

4.10.1 General Requirements

The general skills required to operate a water fluoridation plant are the same that are required to operate a water treatment plant. For this reason, the Regulations call for the operator of a water fluoridation plant to have a classification of at least Class III, in accordance with the classification system for water-care plant operators of the Department of Water Affairs and Forestry (DWAF, 1985). For a continuous water treatment system running three shifts, this requires four or five operators with this classification. The practical implementation of this regulation is not clear. The following are but two examples of the questions that could arise:

- Are these operators dedicated to the fluoridation plant, or does it imply only a Class III operator somewhere on the entire treatment plant?
- What are the implications if such a person is not available, and what are the penalties involved? Should fluoridation then be interrupted?

The National Fluoridation Committee was asked by the project team to provide some guidance on this point. Their position is that continual physical presence of a Class III operator is not required except for making the fluoride measurements once per shift or once per day (depending on the measurement method adopted).

It is difficult to get a measure of the number of suitably qualified operators in the marketplace. In the case of Cape Town, there are not enough Class III operators to man every treatment plant (11 in total) for every shift (Pieterse, 2003). In Port Elizabeth (7 plants in total), there are currently vacancies for 7 operators and 3 superintendents. Rand Water states that they do not have Class III “operators”, those who have qualified to this level are employed at a supervisory level (Xaba, 2003). In general, there seems to be a problem for water treatment plants in general to attract suitably qualified operating personnel.

The staffing requirements of the Regulations will not be met without considerable difficulty due to a difficulty in the recruitment, training and retention of water treatment plant operators.

4.10.2 Specific Requirements for Water Fluoridation

The need for specific fluoridation training is underscored by a recent survey amongst 1280 water fluoridation plants in the US (Lalumandier *et al*, 2001). Only two of the 14 states participating in the survey require one day of fluoridation training per year (Colorado) or every second year (Massachusetts). In the other states, the fluoridation training, if any, is mostly covered within general ongoing training programmes. The survey showed that 41,2% of the operators in the states with mandatory fluoride training could maintain the dosage within 0,1 mg/l of the target, as opposed to 24,5% of the operators not receiving mandatory training. The Centers of Disease Control (CDC) recommends a minimum of one day (six hours) of fluoridation training every year, and is concerned that the level of training in the US is too low. Specifically:

A properly trained operator will know when the metering pump is the wrong size, when the chemical order is incorrect, how and when to test for fluoride properly, how to recognise variations in the fluoride level, and know how to immediately correct the variations. All water plant operators should receive start-up and annual training from the state drinking water engineers. The state engineers, in turn, should be trained in all aspects of water fluoridation, to include the public health benefits of water fluoridation and the role of water plant operators in providing those benefits.

In 1999, an amount of about R5m for the next year was set aside to assist US water providers to develop or upgrade their fluoridation systems, and to allow technical training for water fluoridation (Centers for Disease Control, 1999).

The necessity of comprehensive and accredited training for all technical personnel dealing with water fluoridation is clear. There are currently no local training and certification facilities for water fluoridation plant operators, indicating a definite need for specific, specialised training to quickly establish a local pool of operating expertise prior to the introduction of water fluoridation.

4.11 Cost estimates

Costing of the fluoridation installation is no different than the costing of other chemical dosing facilities at water treatment plants where the main considerations are the cost of providing the installation (capital costs) and the cost of operating the installation (operational costs).

Capital costs will include all costs associated with the design and construction of the plant as well as providing the infrastructure and equipment to comply with the reporting requirements of the Regulations. The costs may therefore include:

- Design fees due to the relevant civil, mechanical and electrical consultants for the design of the facility and the preparation of the required tenders and contracts.
- Fees due to environmental and architectural consultants should their services be required.
- The cost of providing the necessary civil, mechanical and electrical infrastructure and facilities as well as the required dosing and monitoring equipment.
- Fees due for construction management and supervision to the relevant project managers.
- Additional equipment in the analytical laboratory that will be concerned with monitoring of and reporting on the fluoride levels in the treated and distributed water.

Operating costs will include:

- Chemical costs
- Additional staff for the operating of the fluoridation facility as well as for the monitoring of the fluoride levels and the handling of the reporting requirements.
- Maintenance costs of the fluoridation facilities and equipment.
- Maintenance cost of the monitoring and analytical equipment.
- Provision of safety clothing and equipment
- Training of operators in the operation of the fluoridation facility and the requirements of the Regulations.
- Development, implementation and maintenance of an operational plan as required by the Regulations

Information supplied by three major water suppliers has made it possible to determine and compare approximate fluoridation costs. Figure 4-1 shows the unit costs as determined from data provided by Cape Town, the Nelson Mandela Metropole and Rand Water. The graph reflects the unit cost of fluoridation based on total cost of fluoridation for the suppliers over the total production of the supplier. Although there are discrepancies in the way in which each of the suppliers have determined the cost of fluoridation, the cost seems to converge to the 2 to 2 ½ c/kl band for large water treatment institutions. Costs will increase for smaller institutions as can be seen in the next paragraphs.

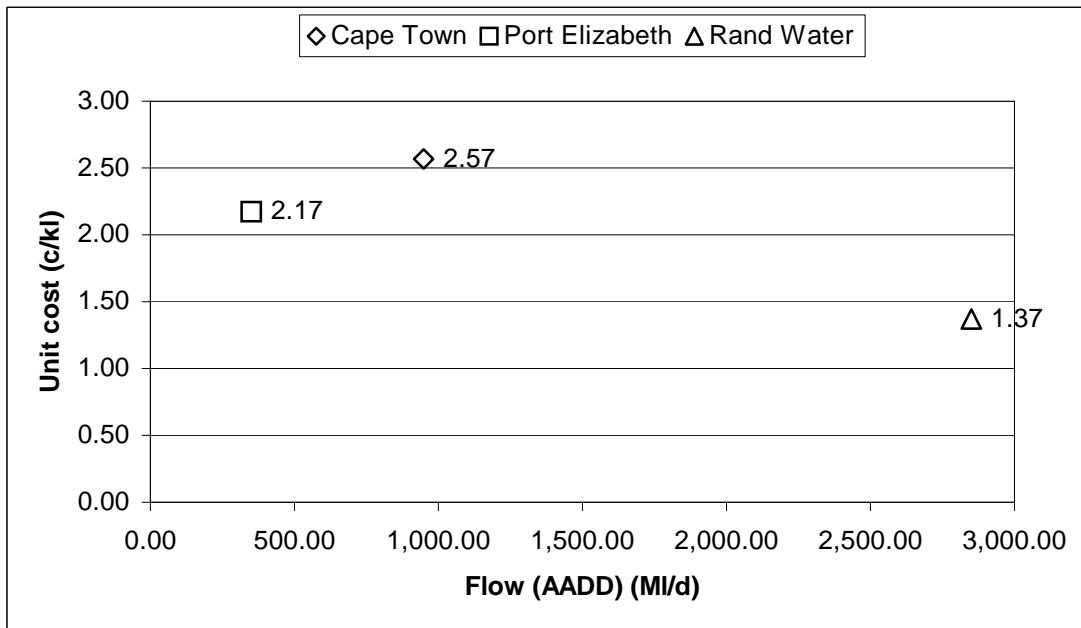


Figure 4-1: Fluoridation unit costs for large water treatment institutions, shown as a function of their average annual daily demand (AADD)

Figures 4-2 to 4-5 describe the capital costs and operational costs for each of the individual plants operated by Cape Town and the Nelson Mandela Metropole that might apply fluoridation. This evaluation provides for an estimation of fluoridation costs for smaller water providers. Figures 4-2 and 4-4 relate to the annual repayments on the capital required to provide the fluoridation infrastructure and are based on a 15-year repayment period at 17%. The graphs show a rather significant difference in the cost estimates of the different suppliers. This is a function of a number of factors ranging from availability of existing infrastructure for re-use as fluoridation facilities to the over or under estimation of capital costs. Figure 4-4 illustrates that these discrepancies are most obvious for plants with capacities under 20 to 30 MI/d.

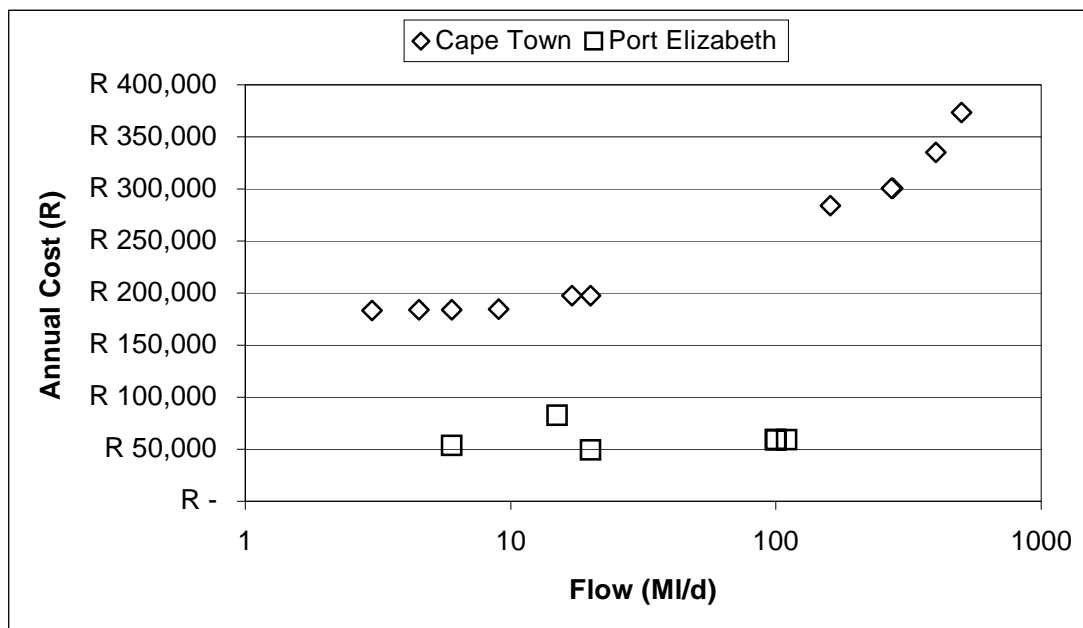


Figure 4-2: Estimated annual capital repayments on the provision of fluoridation facilities for individual plants.

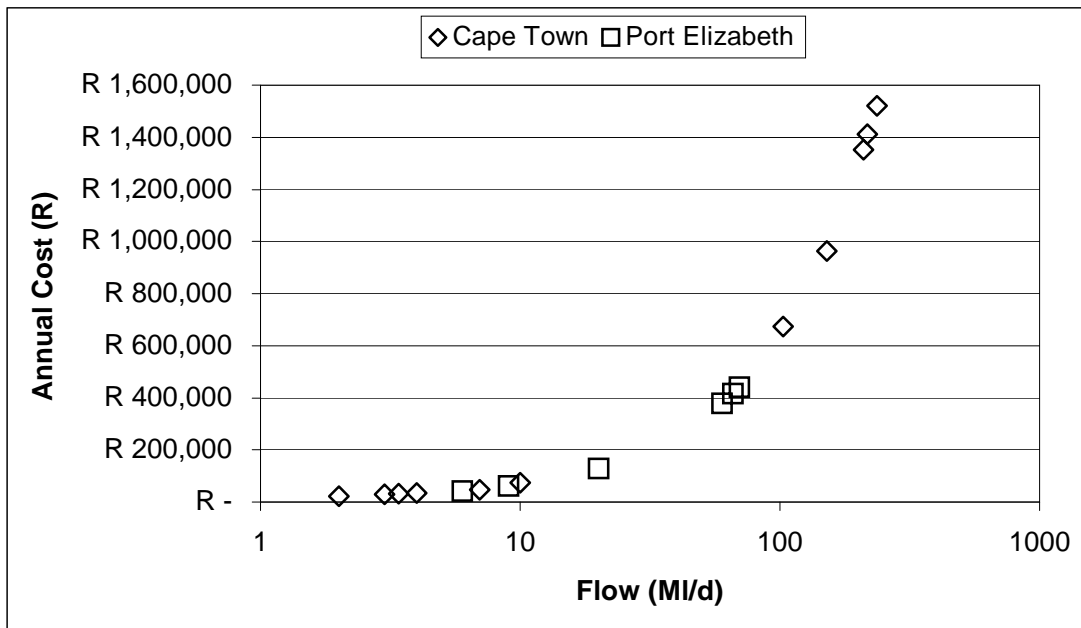


Figure 4-3: Estimated annual operational costs of the fluoridation facilities at individual plants

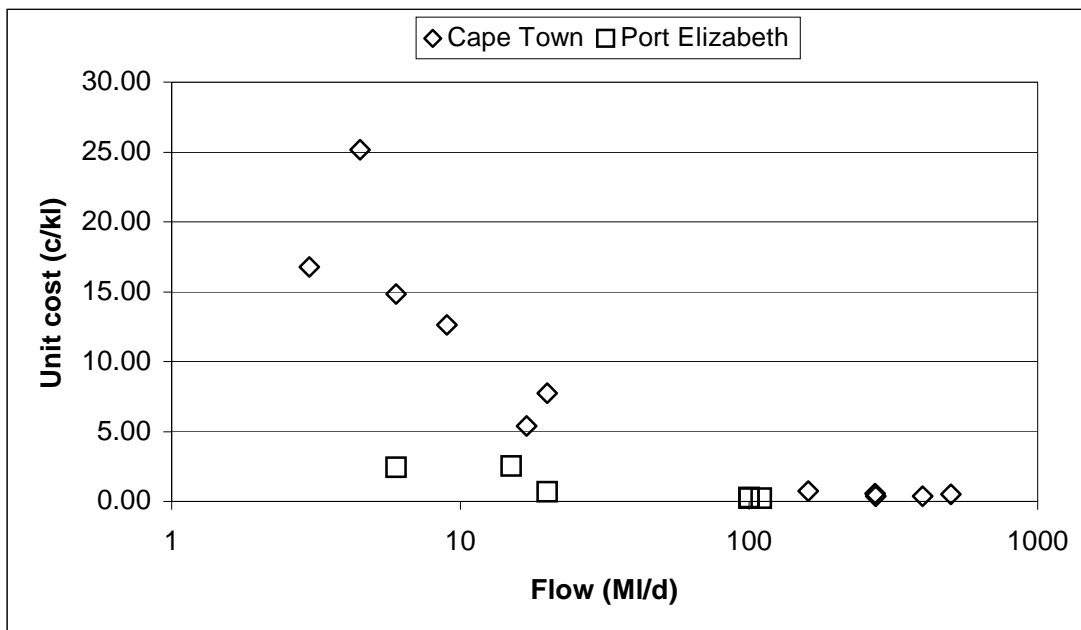


Figure 4-4: Estimated annual capital costs expressed as unit costs for individual plants

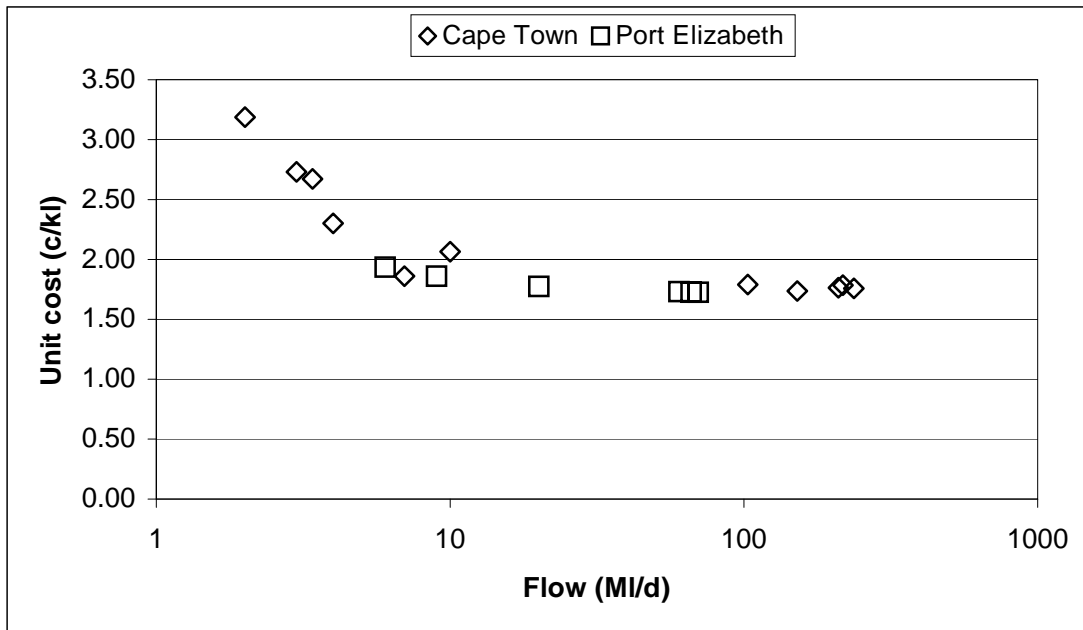


Figure 4-5: Estimated annual operational costs expressed as unit costs for individual plants

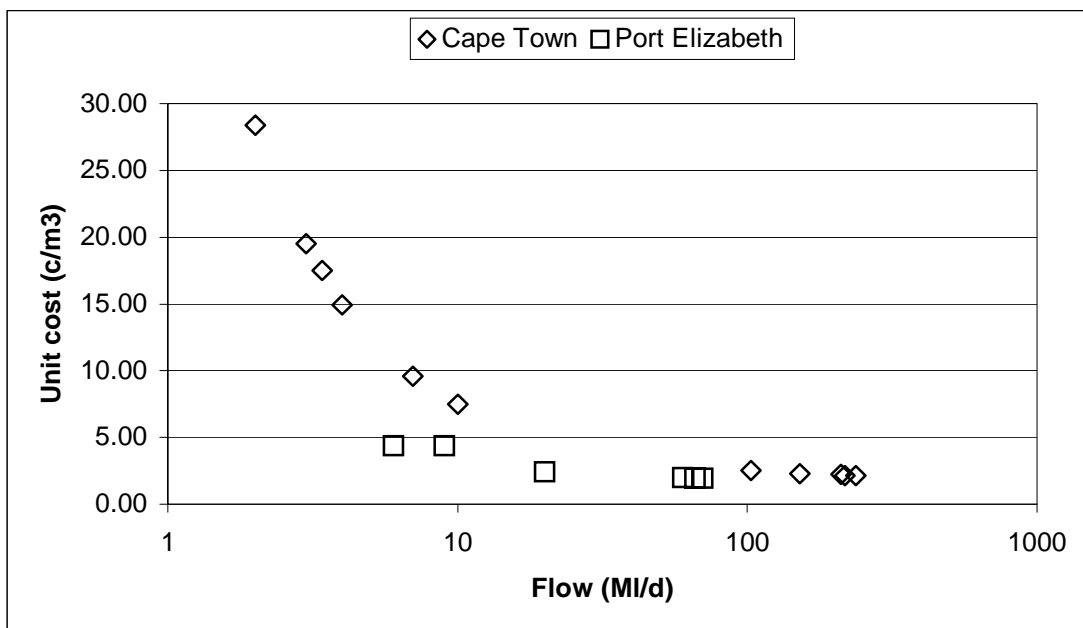


Figure 4-6: Total fluoridation costs per plant expressed as unit costs

Above this capacity the unit cost is virtually constant at less than 1 c/kl for all plants despite the difference in the estimation approaches used by the two water suppliers.

Figures 4-3 and 4-5 indicate that the operational cost estimates are more consistent. Above 10 MI/d the cost appears to be constant at slightly less than 2 c/kl. Figure 4-6 shows the combined capital and operational costs for the individual plants. The discrepancies in capital costs apparent earlier is virtually eliminated when total cost is considered due to the fact that the largest portion of the annual cost is practically fixed as it

relates to chemical costs. Chemical costs make up 90% of the operational cost in larger plants and as much as 50% in the very small plants.

In general costs are not included for the development and implementation of the operational programme and also for the training of the operators. Although these costs do not make up a substantial fraction of the costing of a fluoridation facility, the provision therefore will contribute largely to the successful operation of fluoridation plant.

For water fluoridation plants with a treatment capacity above 10 MI/day, the unit cost of fluoridation is relatively constant at about 2 c/kl, with the cost of the chemical making up about 90% of the total cost. Below a treatment capacity of 10 MI/day, the total cost increases rather sharply as the capital costs make up an increasing share of the total cost.

4.12 Summary, conclusions and recommendations

4.12.1 Summary and Conclusions

- The three fluoride compounds legislated for use in South Africa are commonly used throughout the world and thoroughly covered by standard specifications.
- The larger water suppliers, should they implement water fluoridation, will probably use fluorosilicic acid as the fluoride compound of choice.
- The South African fluorochemical industry is confident that it can already produce this compound at acceptable quality and in adequate volumes to meet the projected water fluoridation needs.
- Delivery of the product will probably be by a number of dedicated bulk road tankers.
- South African road traffic legislation is adequate to enforce the safe, responsible transport and delivery of fluoride compounds by road to site.
- The storage, dilution, pumping and metering of fluoride at the water fluoridation plant do not require any additional design, construction and operating skills above those already available at water treatment facilities.
- There are numerous safety and disaster prevention devices suggested which normally do not form part of regular chemical dosing equipment at water treatment facilities. These require special attention during the implementation phase.
- The allowable tolerances for fluoridation dosing accuracy are strict and continued compliance will require special care and diligence.
- The single most difficult aspect of fluoridation control seems to be the accurate measurement of fluoride in water, a conclusion also borne out by inter-laboratory comparisons as well as operating experience from others who have been practising fluoridation for many years.
- The chemical reactions between fluoride and other compounds are well studied and can be quantitatively anticipated for specific situations.
- A potential problem of fluoride precipitation exists when fluoride is added in a high pH regime, or when fluoride is added at low pH in the presence of aluminium (possible in typical Cape waters).
- No downstream corrosion or other adverse effects on consumers are anticipated.
- An elaborate procedure is detailed for routine administration, in terms of the frequency and hierarchy of reporting.
- No standard formats and electronic backup requirements for the different reports are specified, which may make further reporting or analysis unnecessarily tedious.
- The incident management and reporting procedures are sparsely detailed and may require further amplification.

- In the legislation and guidelines, much emphasis is placed on having a detailed, formal, written programme which will be the blueprint for all employees at all levels for dealing with normal operation, maintenance and disaster management – without giving any guidance on what is required. The development of such a comprehensive plan by each water provider is a costly exercise. There is a need for a generic blueprint programme, which can be amplified and adapted, to the specific needs of each water provider.
- The general Class III operator qualifications required are high and, depending on how the regulation is interpreted, may be a limiting factor to prevent widespread implementation of water fluoridation in South Africa.
- There is a definite and urgent need for fluoridation-specific training and certification for operators, prior to the full-scale implementation of fluoridation in South Africa.
- The total cost of water fluoridation seems to converge at about 2 to 3 c/kl for treatment plants larger than about 10 Ml/day. For plants smaller than 10 Ml/day, there is a sharp increase in unit costs due to the larger proportional capital cost component.

4.12.2 Recommendations

- Design and implement a comprehensive training and certification programme for operators, designers and managers of water fluoridation systems
- Revise and upgrade the Technical Manual to comprehensively reflect South African legislation, local concerns and reporting requirements.
- Establish a benchmarking and networking system amongst water providers to improve the measuring accuracy of fluoride to ensure compliance to the strict dosage control ranges called for; alternatively, consider less stringent dosage control ranges.
- Develop a uniform and preferably electronic reporting system for automated submission and rapid review of water fluoridation records.
- The Regulations and Technical Manual require the submission, by each water provider, of a comprehensive programme that deals with all aspects of water fluoridation at all levels. As there are no guidelines or minimum requirements for this programme, it is recommended that a generic water fluoridation programme is developed to the satisfaction of the Departments of Health and Water Affairs, which can then be used as a standard template by the different water providers to detail their own programmes in a cost-efficient, time-efficient and uniform way.
- Assemble the typical water quality profiles at those South African water providers slated for water fluoridation, and systematically model the chemical speciation upon fluoride addition with a program such as MINTEQA2. This will demonstrate to what extent the concerns about aluminium and other complexes with fluoride are warranted.

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CHAPTER FIVE ECONOMIC ISSUES

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5.1 Introduction

During the last 50 years most economically developed countries of the World, and many developing countries as well, have weighed up evidence on the use of fluoride to reduce tooth decay (www.doh.gov.za, 2003). Medical evidence shows frequent exposure to small amounts of fluoride each day is the best method for reducing tooth decay in all age groups and social classes, and especially amongst children (see McDonagh et al, 2000 and Chapter Two of this report). However, there is great debate over how to achieve this exposure (www.doh.gov.za, 2003; Connet, 2001; www.randwater.co.za, 2003; www.edoc.co.za, 2003)

Two schools of thought have emerged (www.thecommunityguide.org, 2002). One is that consumers be educated and encouraged to increase their intake of fluoride up to the appropriate level (with fluoridated toothpaste, fluoridated foods, fluoridated tablets, etc.). The other is the administration to consumers of a desired dose of fluoride irrespective of their tastes on the issue. The primary method of distribution advocated by the latter school is through the addition of a fluoride compound to the drinking water of the targeted communities.

Letting consumers choose has the advantage that fluoride is not wasted and imposed on unwilling consumers and the environment. Distributing it through the drinking water has the advantage that its reach is greater and therefore also the scale of benefit. Possibly this method of distributing the fluoride is the most cost-effective way of achieving this scale of reduced tooth decay benefit (see Table 5; www.doh.gov.za, 2003; South African Government Gazette, 1997).

By the year 2000 the latter school of thought had won favour in South Africa, and in September of that year the Department of Health legislated that the potable water distributed by water authorities in South Africa be fluoridated to a maximum level of 0.7 milligrams per litre.

The implementation of the health policy on fluoride concentration has, however, been stalled by opposition to it from some members of the public and key water distributing authorities. Foremost amongst these authorities is the Rand Water Board (www.randwater.co.za, 2003). The Rand Water Board oppose this policy because they argue it fails to take into account negative health impacts and natural resource damage due to fluoride accumulation processes in rivers and dams. They point out that less than 1% of the water they would fluoridate would be drunk. The remaining 99% of the total would be imposed on the other users of water and the environment.

5.2 Methodology

The methodology selected for this reflection was cost benefit analysis (CBA). CBA is one of the main economic methods for assessing the merit of a project or policy. It entails accounting for and comparing in the same analysis all of the expected costs and benefits of alternative courses of action.

In this case the costs and benefits that are required to be compared are those expected to occur if the fluoridation policy were to be implemented with those that would otherwise be expected to occur. As is

convention in CBA, the implementation of the fluoridation policy will be referred to as the fluoridation project in the foregoing analysis and the situation if it were not implemented will be referred to as the base case.

Two projects were selected to apply CBA to. Both relate to the scientifically administered addition of hydrofluosilicic acid to the drinking water of South Africans in order to achieve a fluoride concentration in the water of 0.7 mg/l. One covers the case of a person living in a large metropolitan area and the other covers the case of a person living in a small rural community (comprised of less than 5 000 people), i.e., the projects are at opposite ends of the population scale. This selection was based on the findings of other studies that population size was a critical factor in the economics of these projects (see Table 5-1).

International literature documents the main expected benefit of the project as reduced tooth decay and the main expected costs as purchases of plant, chemicals and personnel to administer the chemicals (see Tables 5-1 and 5-2 below). Other costs identified are negative health impacts and natural resource damage (Table 5-3 and 5-4).

5.3 Setting the parameters for the cost-benefit analysis

The following assumptions are made:

- A time horizon for the project will be set at 60 years. Given that the primary benefit is a health one, an appropriate time horizon for this project is the life expectancy of a South African. Currently this is about 60 years, but it is expected to decrease as a result of the aids epidemic (SAIRR, 2000).
- The probability of survival of the South African population will be assumed constant over the 60 years and used to weight the project benefits and costs as identified in the respective years. Projections suggest that there will be substantial declines during the next 10 years in the proportions of the population aged 25-50 (SAIRR, 2000).
- Discounting will be with respect to year periods and a social discount rate of 10% will be assumed. This rate is derived as an average of several real per annum rates of return over the passed 5 years. Currently the long-term real rates are less than half of this. Sustainability issues do not appear to be of great significance and were not taken into account in the setting of this rate. The main intergenerational issue appears to be the willingness of the current generation to pay the next generation's costs of averting possible negative health impacts (see Table 5-3).
- South African valuations will be preferred over international ones, but ratios found internationally will be deemed applicable to South African circumstances.

5.4 Expected costs of this project

CBAs on this topic describe the expected costs of projects in one of two ways: expected costs per person (see Tables 5-1, 5-2, 5-3 and 5-4 below) and expected costs per averted Decayed, Missing and Filled Teeth (DMFT) (see Table 5-5). The connection between the two is the relative frequency of a DMFT averted per person per year. This varies according to fluoride concentrations in the drinking water and age, inter alia.

Table 5-1 Expected operational and capital costs in US dollars (and at 1997 levels unless indicated) of the project in all years per population size served by distribution plant per capita per annum – international perspectives¹

Study – location	Per capita cost (\$) population < 5 000	Per capita cost (\$) population between 5 000 and 20 000	Per capita cost (\$) population > 20 000
Kohn, et al (2001) United States	7.62 (1999)		0.72 (1999)
Garcia (1989) United States	1.46	0.94	0.27
Kallis (1976) Australia	4.63		
Ringelberg (1998) United States	3.27	1.41	0.52
Donovan (2000) Canada*			0.66 (1998) (operational costs) 0.99 (1998) (operational costs plus damage costs to aquatic animals)

Notes:

¹ Capital rentals are calculated as the product of the value of capital and the discount rate. The latter varied per year, per country and per study. They ranged between 3% and 10%.

* Estimated from Donovan's figures, the current US to Canadian \$ exchange rate and the 1996 census population total for Calgary, Canada (811 400).

From Table 5-1 the following deductions were drawn:

- Per capita operational and capital costs differ widely between different locations. For the four studies referred to in Table 1, the per capita operational and capital costs per annum for populations greater than 20 000 average \$0.54 or R4.32 at an exchange rate of R8 per \$. For the four studies referred to in Table 5-1 the per capita operational and capital costs per annum for populations less than 5 000 average \$4.25 or R34 at an exchange rate of R8 per \$, i.e. almost 8 times more.
- Per capita operational and capital costs of the fluoridation project decline as the total population served by it increases. For this reason the CBA can be expected to favour fluoridation projects serving larger size populations.
- Natural resource damage is related to fluoride accumulation in aquatic animals and can push costs up substantially in some cases (48% in the case of Donovan's Calgary study).

Table 5-2 Expected operational and capital costs in Rand (2001 – 2003 price levels) of the project in all years per 1095 000 000 kilolitres water (3 000 000 daily) fluoridated per major metropolitan area per annum – a Rand Water perspective

Nature of Cost	Cost (R/annum)	% of total
Chemicals	9 351 000	63
Plant - capital redemption (at 13,47% per annum rental rate)	3 298 700	22
Plant – maintenance	950 000	6
Personnel	1 322 000	9
Total	14 921 750	100

Source:

www.randwater.co.za (2003) who in turn based their estimates on a study conducted during 1996 for five different water fluoridation plants for The Metropolitan Water District of Southern California. The requirements of this water district are similar to those that would be required by the Rand Water Board.

From Table 5-2 it is deduced that the purchase of chemicals makes up most of the cost of fluoridation, but it is unclear how many people would be reached through the Rand Water Board fluoridation project. Not all of the Gauteng's 8.7 million inhabitants have access to Rand Water Board water. The Board's estimates of the operational and capital cost range from R0.13 per person per annum to R4.93 per household per annum (or R0.99 per person for five person households consuming 30 kilolitres per month).

In Chapter Four of this study, the total cost of fluoridation per kilolitre of water in the area served by the Rand Water Board is estimated at R1.37. This estimate is lower than those for Cape Town and Port Elizabeth, which are R2.57 and R2.17 respectively. Chapter Four concludes that the total costs of fluoridation per kilolitre of water converge at between 2.0 and 2.5 cents/kilolitre. Assuming 5 person households and consumption of 30 kilolitres water per month per household, this cost translates to between R1.44 and R1.80 per person per annum. The Department of Health estimate this cost at about R1 per person per year (www.doh.gov.za, 2003).

If all of Gauteng's 8.7 million population would be reached by the Rand Water Board's fluoride distribution system, the average social cost of the fluoridation project per annum per person would be about R1.72 (i.e. the cost of R14 921 750 divided by the population of 8 700 000). This cost is lower than that cited in international literature for large or small populations (see Table 5-1) but falls within the range that is consistent with the findings of Chapter Four.

Based upon the figures shown in Chapter Four, it is further deduced that these costs only apply in areas served by fluoridation plants that process in excess of 10 000 kilolitres of water per day. For each 1000 kilolitres of water fluoridated per day less than this the costs per kilolitre increase by about 3c. For a mid-size plant fluoridating about 6 000 kilolitres of water the costs per kilolitre would be about 14.5c and for a small-size plant fluoridating about 2 000 kilolitres per day the cost per kilolitre would be about 26.5c.

Table 5-3 Potential health costs per person per annum in Rand of the project

Nature of Impact	Minimum per capita willingness to pay cost of averting negative health impact of the project with no aversion expense¹	Assumed treatment cost impact period
Dental Fluorosis	Extra costs of treating dental fluorosis	7 < age < 30
Immune and thyroid system disturbance	Extra costs of treating disturbances	20 < age < 60
Kidney damage	Extra costs of treating kidney disease	20 < age < 60

Source: www.randwater.co.za, 2003; Hileman (1988); Colquhoun (1997: 6–7)

Note:

¹ The person would be prepared to pay more than this because there are many other costs related to these diseases (quality of life impacts).

In an attempt to avert some of these negative health risks it is likely that some of the population would choose to de-fluoridate their drinking water. The Rand Water Board have estimated the costs of de-fluoridation in South Africa to be R5.50 per kilolitre using reverse osmosis and R1.80 per kilolitre using activated alumina. Presumably the latter would be the preferred method because it is cheaper. This choice will not eliminate the potential negative health cost from excess fluoridation to the remaining consumers, nor to the environment.

Table 5-4 Potential environmental costs per person per annum in Rand of the project

Nature of Impact	Potential cost of environmental impact of the project with no aversion expense	Potential cost of project – in the form of expense to avert negative project impact	Estimated years where impact occurs
Damage to aquatic life though excess fluoride accumulation in rivers and dams	Reduced recreational appeal of river and dam systems	De-fluoridation / dilution costs at selected points and times in rivers and dams	1 < age < 60

Source: www.randwater.co.za (2003); Hirzy (1999).

Negative health and environmental impacts are considered likely (see Health and Environment reports and Liteplo et al, 2002).

Less certain than the negative health impact is the environmental impact. The Rand Water Board argued that part of the environmental impact would be increasing the fluoride content of rivers to water users downstream of them (www.randwater.co.za, 2003), but is this impact an external benefit or an external cost? Another uncertainty with respect to the environmental impact is whether it is not more appropriately captured as an indirect health cost.

In order to meet the requirement to be fully inclusive it is almost always necessary in CBAs to make subjective decisions. In the light of the evidence currently available in South Africa on the costs described in Tables 5-3 and 5-4, this author has chosen only to allow for a cost of averting the negative health impacts of fluoridation (not the costs of the negative impacts and the costs of environmental damage). In this connection it was assumed that 5% of the drinking water would be de-fluoridated. For the population served by the Rand Water Board this would amount to 5% of the daily 19 000 kilolitres water at a charge of R1.80 per kilolitre (www.randwater.co.za, 2003). As an average per annum per person charge this would be : $(5/100 \times 19\ 000 \times 365 \times R1.80) / 8\ 700\ 000 = R0.72$. This charge will be deemed applicable in this CBA for the years 1-60.

Another method of reporting the costs of fluoridation is as the cost of an averted DMFT. Table 5-5 shows estimates of these costs.

Table 5-5 Costs of an averted DMFT

Study	Cost ranges in US \$ of an averted DMFT (corresponding population ranges) ¹	Cost saving per DMFT as percentage of dental treatment costs without fluoridation	Population age in years
Kohn et al (2001) United States	4.71-17.00 at 1999 price levels (cities more than 100 000 to less than 10 000 in number)	77%	-
Birch (1998) United Kingdom ((high caries prone community)	3.54 –10.33 at 1997 price levels (cities more than 600 000 to less than 60 000 in number)		4 < age < 14
Birch (1998) United Kingdom (low caries prone community)	15.69 – 46.65 at 1997 price levels (cities more than 600 000 to less than 60 000 in number)		4 < age < 14
Doessel (2000) Australia		50% tot 90%	6 < age < 14
Dowell (1974) United Kingdom		55%	3 < age
Niesen (1984) United States		5% to 50%	all school children

Notes:

¹ Discount rates of between 3 and 10 % were used to determine capital costs

The cost of averting a DMFT varies widely according to the country, the population whose drinking water is fluoridated and the prevalent incidence of caries. The average cost aversion for high populations where there is mixed caries incidence is about \$8 for the first three studies reported in Table 5-5.

It is estimated that on average a person in South Africa exposed to drinking water with a fluoride content of about 0.2 mg/l will experience 1 DMFT every second year (Brown, 2003). Some of these will be averted through the fluoridation of drinking water. It is deduced that a DMFT would be averted in South Africa about once every 5 years on average (estimated from the information in Table 5-5 and from information supplied by Brown, 2003).

5.5 Expected benefits

Table 5-6 Expected benefits per annum per DMFT

Benefit	Incidence per annum	Unit valuation
Reduced professional care costs of caries treatment	0.2	US \$65 (1999 price levels) Kohn et al (2001) R108.90 – R209 (RAMS scale of benefits, 2003)
Reduced personal expenses (costs of travel and time) for additional caries treatment	No estimate available	travel cost
Willingness to pay for healthier teeth – aesthetic and discomfort reduction	No estimate available	Contingent Valuation necessary
Savings in current outlays on sodium fluoride tablets	No estimate available	

There is little doubt that there are more benefits derived from fluoridation than the professional dental costs saved, but data on which to base these estimates were unavailable. It is assumed that the average cost saved per averted DMFT in South Africa is the average cost of a small and large filling at RAMS scale of benefit rates, namely $[R108.90+209.00]/2 = R158.95$. If one DMFT per person would be averted through fluoridation every 5 years (see calculations with respect to Table 5-5) the per person cost saving per annum would be:

$$R158.95/5 = R31.79$$

Table 5-7 Summary expected cost profile per annum per capita assuming constancy over 10 year cycles, large metropolitan populations to distribute water to and a 60 year time horizon (2003 price levels)

Year	Operation and Capital expenses (R/annum)	Health cost aversion expenses (R/annum)	Probability of health cost being experienced – rate of survival	Expected cost (R/annum)
0 – 9	1.72	0.72	1.00	2.44
10 – 19	1.72	0.72	0.97	2.42
20 – 29	1.72	0.72	0.82	2.31
30 – 39	1.72	0.72	0.63	2.17
40 – 49	1.72	0.72	0.42	2.02
50 – 59	1.72	0.72	0.25	1.90

Note: Survival rates were estimated from age profiles (www.statssa.gov.za, 2003)

Table 5-8 Summary of expected benefit profiles per annum assuming constancy over 10 year cycles, large metropolitan populations receiving water and a time horizon of 60 years (2003 price levels)

Year	Saving of dental treatment costs for 10 years (R)	Probability of benefit being experienced – rate of survival	Expected benefit (R)
0 - 9	0.00	1.00	0.00
10 - 19	31.79	0.97	30.84
20 - 29	31.79	0.82	26.07
30 - 39	31.79	0.63	20.03
40 - 49	31.79	0.42	13.35
50 - 59	31.79	0.25	7.95

Note: Survival rates were estimated from age profiles (www.statssa.gov.za, 2003)

Based upon the information contained in Tables 5-7 and 5-8 and the assumption of a 10% discount rate the following CBA decision criteria were generated: Benefit Cost Ratio (BCR) and Internal Rate of Return (IRR). A BCR >1 and IRR > the discount rate (10%) are considered recommendations for a project. Based upon the above information:

$$\text{BCR} = 105.41/23.95 = 4.4 > 1$$

$$\text{IRR} = 29\% > 10\%$$

Result = favourable for a project serving large metropolitan populations

For small rural populations (less than 5 000 people) and small plants (fluoridating less than 2000 kilolitres per day) the operational and capital costs per capita increase substantially – an analysis of other studies (see Table 5-1) and the Technical report of this study suggest at least eight times more. Under these circumstances the following CBA decision criteria are yielded:

$$\text{BCR} = 105.41/143.91 = 0.73 < 1$$

$$\text{IRR} = 5\% < 10\%$$

Result = unfavourable for small rural populations

5.6 Conclusion

The efficiency case for fluoridation projects serving large metropolitan populations is supported by a comparison of expected cost and benefit data of the project and base cases. The discounted benefits are over four times the discounted costs and the IRR is well in excess of the social discount rate. However, for small populations (less than 5 000) the project is inefficient when compared to the base case. The discounted costs exceed the discounted benefits and the IRR is less than the discount rate. These conclusions are made subject to a number of uncertainties, strong assumptions and omissions. The main omission is the negative health cost. This omission amounts to assuming it to be zero.

5.7 Recommendations for further research

The following recommendations flow from the analysis presented in this chapter:

- The fluoridation project is efficient in large metropolitan areas in South Africa if the intended dosage is indeed safe (has no negative health impacts), but it is inefficient in very small rural communities. It is deduced that at some intermediate population size the project becomes efficient. A more comprehensive CBA should be undertaken to determine this size.
- There is little doubt that the main limitation of this study is the lack of information on the negative health costs at fluoridation concentrations between 0.5 and 1.0 mg/l. This lack of information creates too much uncertainty and will cause CBAs to yield inconsistent results. There are grounds for assuming scientists having got their sums right and that it is safe to fluoridate water between 0.5 and 1.0 mg/l. In this case there are no negative health costs to worry about. However, some uncertainty remains in this regard, as pointed out in Chapter Two of this report.

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CHAPTER SIX

SOCIAL AND LEGAL ISSUES

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6.1 Introduction

This section of the report deals with the feasibility of using water for the distribution of fluoride from a legal and social perspective. It looks at the central legal and ethical debates that have been raging over the past 50 years, and the relevance these debates may have for a South African context. It also looks at the current regulations, how they were made, and what possible legal challenges could be brought against them.

In terms of the social aspects of fluoridation, the report has looked at a series of questions such as:

- Who are the intended beneficiaries, and how effective is water fluoridation likely to be in achieving its stated aims?
- What is the likely effect of water fluoridation on socio-economic disparities in dental health in South Africa?
- What are the levels of and requirements regarding public awareness of water fluoridation in South Africa?

It is perhaps instructive to begin the section with a brief look at the outcome of the Taskforce on Fluoridation appointed by the Lord Mayor of Brisbane in Australia, in order to illustrate the degree of controversy surrounding the debate. On joining the Taskforce, 10 members supported water fluoridation, 5 opposed, and 2 were uncertain. At the end of the 10 month Taskforce process, 9 members opposed fluoridation while 8 members supported. An analysis of the shift in opinions between the beginning and end of the Taskforce process revealed that none of those strongly supportive or opposed at the start of the process had altered their views (although those opposed to fluoridation indicated that their opposition had hardened).

6.2 International legal and ethical debates

Over the past 50 years, several key legal and ethical issues have emerged in the fluoride debate. The following section introduces some of these legal and ethical debates, and debates their merits in a South African context.

The conventional view is that policy-makers are presented with a clear moral choice when weighing the benefits and harms associated with water fluoridation. However, the ethical debate is split between those who say that the benefits to the general population outweigh the potential dangers and any infringements on individual autonomy, and those who believe that most if not all the claimed benefits can actually be attributed to alternative factors in dental hygiene and diet, and who raise concerns about the possible side-effects of water fluoridation.

6.2.1 International Extent of Fluoridation

Legislation authorizing the adjustment of water fluoride concentrations can be mandatory, as in South Africa, Israel and Ireland¹, and require that communities of a certain size fluoridate their water supplies if natural fluoride levels are low. The alternative is for enabling legislation, which authorises the Ministry of Health or a local government to introduce fluoridation. Some countries, such as the USA and Canada, may allow or require a popular vote before implementing water fluoridation.

Fluoridation of water supplies is largely confined to the English-speaking countries, the Soviet Union, and some Latin American nations. Estimates of the number of people who consume artificially fluoridated water worldwide, range from a 1988 estimate of 250 million to a current estimate of 360 million². Of these, approximately half live in the US and Canada, about 50 million in Brazil, and 40 million in the Soviet Union. However, less than 1% of the population of continental Western Europe has artificially fluoridated water. The remaining 99% of western continental Europe has rejected, banned, or stopped fluoridation due to a variety of reasons, including environmental, health, legal or ethical concerns.³

In Europe, the most common method for the distribution of fluoride to the population is through fluoridated salt.⁴ Countries with fluoridated salt on the market include Germany, France, Belgium, Spain, Austria, Switzerland, and the Czech Republic. Fluoridated salt is also provided in Mexico and Chile.⁵

6.2.2 Common ethical challenges

The basic argument in favour of water fluoridation is that the state ought to act to achieve fundamental benefits for its citizens. The main arguments can be grouped as follows: the compulsion objection, the safety objection, and the equity debate. These and other related questions will be explored in this section.

6.2.2.1 Compulsion objections

"Does the state have the ethical and legal right to impose compulsory medical interventions on the population without consent, regardless of the efficacy of the intervention in the protection of some aspect of public health?"⁶

While the right of the state to intervene in the prevention of contagious diseases is widely accepted, it is felt by opponents of water fluoridation that the danger imposed by dental decay is not sufficient to justify the compulsory administration of fluoride through the water supply system. In this view, fluoride is a preventative medication used to prevent the occurrence of dental disease. However, administered through the water supply, it becomes compulsory medication, and therefore an infringement of fundamental human rights.

¹ In Ireland, the decision to make the legislation governing water fluoridation mandatory was considered the most satisfactory option by the Minister for Health. It would impose a statutory obligation on local authorities to fluoridate public water supplies, whereas enabling legislation would leave the ultimate decision either to local sanitary authorities or to local health authorities. Problems with enabling legislation included operational difficulties where water supply boundaries overlap, and adjacent water authorities have different fluoride policies. Department of Health officials also believed that if the issue to fluoridate water was left to local authority members, some of them were likely to be 'misled and fall victims to the horrific arguments with which propagandists of the "pure water" school would assail their conscience as well as their ignorance'. (Irish Forum on Fluoride, 2002)

² Connet, 2002; ADA, 2002; Hileman, 1988; Irish Forum on Fluoride, 2002, Brisbane Taskforce, 1997.

³ See Appendix 1 for a list of countries and their fluoridation status.

⁴ Irish Forum, 2001

⁵ Irish Forum, 2001; Brisbane Taskforce, 1997

⁶ Cross, 2000

Water fluoridation is seen as removing freedom of choice from individuals. While it has been argued that there is still an element of choice, as people can utilize other water sources, avoidance is difficult and costly.⁷

These objections centre on the relationship between the state and the individual, and with reconciling the norms of welfare and paternalism with those of privacy, bodily integrity and human dignity. Opponents of fluoridation focus on the ability of the state to impose treatment for a non-contagious condition. Related concerns focus on the status of fluoride as an essential nutrient or a compulsory mass medication. (See box below.)

Supporters of water fluoridation argue that freedom is not simply about being free from interference, but also entails being free to exercise certain rights, such as the rights to education, basic health and hygiene and so forth. There is debate on whether or not oral health should be included in basic health, and if water fluoridation is the best way to benefit general oral health. However if oral health is included in basic health care, failing to provide this minimum standard becomes unethical. Allowing harm becomes worse than limiting autonomy.

In this view, the reduction of autonomy involved in water fluoridation is seen as justified by the goal of reduced tooth decay in society. Advocates argue that the benefits accruing to society through reductions in dental caries outweigh any harm to individual autonomy, while opponents say that the presence of alternative sources of fluoride means that the benefits of fluoride can be realized without violating the principle of autonomy. The counterargument is that this presumes everyone can access these alternative sources. Advocates therefore also claim that water fluoridation can benefit everyone, regardless of socio-economic status, and therefore promotes social equity.

Supporters of water fluoridation argue that while individual autonomy and parental rights are important, they are not absolute, and comparisons are made with other instances of limiting individual freedom for the public good, such as traffic restrictions and food safety regulations. If it is accepted that the state has an obligation to protect and promote welfare of citizens, it may sometimes be necessary to curtail individual liberty. However, self-determination and the right of parents to choose for their children are values which should not be lightly overridden. Fluoridation can only be ethically justified if it is sufficiently superior to alternatives to outweigh the disadvantages of compulsion.⁸

⁷ Irish Forum on Fluoride, 2001

⁸ Brisbane Taskforce, 1997

Is fluoridation medication, or an “adjustment” of the natural fluoride concentrations?

Arguments for: The European Union has defined a medicinal substance as “any substance or combination of substances presented for treating or preventing disease in human beings or animals...and which may be administered...with a view to making a diagnosis or to restoring, correcting or modifying physiological function in human beings is likewise considered a medicinal product”.⁹ The FDA has also recognized fluoride as a drug, “when used in the diagnosis, cure, mitigation, treatment, or prevention of disease... that is subject to FDA regulation.”¹⁰ Diesendorf concluded that fluoridation at the levels recommended for reducing tooth decay is not an essential nutrient, is not a natural substance, but rather an expensive-to-avoid preventative medication with an uncontrolled dose. According to Dental Didactics, the view of fluoridation as a medication is supported by the fact that fluoridation is usually proposed and advocated by dental and medical professionals, and that numerous fluoride preparations are only available on prescription. The Brisbane Taskforce also produced arguments that as it is intended to produce an improvement in dental health, it is a medication.

And against: The Irish Supreme Court in 1964 rejected the view of fluoridation as “mass medication”. A commission established by the Government of New Zealand found that “fluoride is not a drug but a nutrient and fluoridation is a process of food fortification.” And according to the American Dental Association “Fluoride is not a medicine. It does not treat or cure anything. It is a nutrient that prevents dental decay. Like other minerals in the diet, fluoride helps the body to resist disease, namely, dental decay.”¹¹

The WHO has classified fluoride as a potentially toxic element, but one which may nevertheless have some essential functions at low levels. The problem is that the margin between the positive and negative effects on human health is quite narrow. Total exposure to fluoride, including water, toothpaste and foodstuffs is important, and there is currently very limited data available on total exposure to fluoride. The WHO consultation indicated that total intakes of fluoride at 1, 2 and 3 years of age “should, if possible, be limited to 0.5, 1.0 and 1.5 mg/day, respectively,” with not more than 75% coming in the form of soluble fluorides from drinking water. It was also noted that “adult intakes exceeding 5 mg of fluoride per day from *all sources* probably pose a significant risk of skeletal fluorosis.”¹²

It is impossible to control the *exact* daily dose of fluoride received by individuals through water fluoridation, due to differential water consumption. It is however possible to implement water fluoridation at levels which would ensure that the recommended daily dose would not be exceeded. Care should therefore be taken to implement fluoridation at levels which, given the maximum probable water consumption (possibly based on that of miners where applicable), would still fall within the recommended levels.

6.2.2.2 Safety objection

From an ethical point of view a risk can be justified if it is outweighed by the benefit. However there is considerable debate and little agreement over the risks and benefits associated with water fluoridation (as opposed to the topical use of fluoride, which is overwhelmingly accepted as being beneficial), as discussed in the Health Chapter. If the precautionary principle¹³ were to be followed, fluoridation would most likely not be implemented until further research has been conducted.

⁹ Codified Pharmaceutical Directive 2001/83/EEC, in Cross & Carton, 2003.

¹⁰ Cross & Carton, 2003

¹¹ ADA, 2002.

¹² Litelpo et al, 2002: 184. emphasis added

¹³ According to the Precautionary Principle, when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of

However, the Brisbane Taskforce concluded that it is not unethical to reach a decision under uncertainty. In order to make the best decision in light of this uncertainty, the principle of 'maximising expected utility' is useful, and means taking that course of action which has the greatest total expected benefit. A number of factors are necessary to apply this principle:

- consideration of all possible options;
- examination of possible outcomes or consequences;
- each outcome assigned a probability value and utility value;
- multiply to produce 'expected utility'.

6.2.2.3 The Equality debate: addressing inequalities in health care

According to the 1948 UN Universal Declaration of Human Rights: "everyone has the right to a standard of living adequate for...health and well-being...including...medical care and necessary social services." There is general agreement that basic health care should be distributed equitably, but less on the definition of basic care, especially in context of oral health. Dentistry is a health service accessible only to the more advantaged members of society, yet the loss of teeth and other dental problems tends to be more prevalent, and the consequences more serious, among lower income groups. About a ¼ of the population in North America visit dentists for little more than emergency care, while in SA, over 75% of the black population reported visiting the dentist or dental clinic for symptomatic reasons only.¹⁴ While it is not clear if the lack of emphasis on preventative care is due to poverty, it does raise concerns over the way dental care is offered.

Dental decay is not a condition which is spread equally throughout the population, and there are many individuals and groups who are more susceptible and at greater risk. Water fluoridation is particularly aimed at those who do not or are unable to look after their teeth, for example, young children and those in lower socio-economic groups. If not everyone can access alternative forms of fluoride, then the most vulnerable will miss out on the benefits of fluoride. Fluoridation of water supplies is viewed as an intervention that will therefore benefit everyone regardless of socio-economic status. In this view, water fluoridation promotes social equity.

However in a South African context, where an estimated 7 million people do not have access to a basic water supply, let alone access to a reticulated system of a large enough scale for water fluoridation to be implemented, water fluoridation (if assumed to be beneficial) will not benefit a large portion of the most vulnerable people in our society. Preliminary estimates seem to indicate that, based on the DOH cut-off limit, restricting implementation to those schemes serving more than 60 000 people (see below), roughly 3 million rural people who currently have access to a water supply, will not have access to fluoridated water supplies in the near future. Based on a sample of DWAF rural water supply projects¹⁵, it is possible that at least half of the remaining 7 million people will also be served by smaller schemes, bringing the total number of people who may not receive fluoridated water under the current guidelines to approximately 7.5 million.

If preventative dental health care is assumed to be part of a basic health right, then in the interests of social equity the Government will have to ensure that alternative arrangements (such as other fluoridated products,

proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.

¹⁴ Dharamsi, 2002

¹⁵ See Appendix 2

tooth-brushing schemes in poor areas, education campaigns etc) are made *in addition to* water fluoridation, to safeguard the dental health of communities who will not receive fluoridated water in the interim.

6.2.3 International legal challenges¹⁶

There have been various legal challenges against the fluoridation of water supplies. In Scotland in the 1980's the presiding judge found fluoridation to be safe and beneficial, and found no evidence to support the claim that fluoridation caused cancer. However, the judge upheld that part of the case which claimed that fluoridation was beyond the legal authority of a water authority, and their responsibility to provide a supply of 'wholesome' water.¹⁷ However in New Zealand, a test case on water fluoridation taken to the Privy Council in 1964 confirmed that the power of local authorities to supply 'pure water' has implicit in it a power to add fluoride to the water.

There have been many legal challenges against fluoridation in the US. One survey found that in the five years up to 1984 there had been 255 challenges to fluoridation programs. As a result, 36% of these programs were terminated and 14% delayed or curtailed. A review of referenda in the 1980s found that 63% of 163 community fluoridation referenda failed to pass decisions to fluoridate.¹⁸ Challenges to public water system fluoridation statutes typically include claims of: (1) deprivation of personal liberty; (2) abridgement of individual privileges and immunities; or (3) denial of equal protection of the law.

In the US, the right of state, county or city governments to fluoridate the public water supply is based on the legal premise of performing a publicly beneficial "police action", to reduce the number of dental caries in children. Police power is the constitutional authority allowing states to make laws concerning the health, safety, welfare and morals of its citizens. A widely accepted example of the exercise of police power is the compulsory inoculation of all children against contagious diseases such as measles, mumps and rubella. Medical interventions under police power must rest on reasonable medical or scientific evidence; must be fairly justified by grave cause or public emergency; and cannot be imposed on protesting citizens who are able to prove, "by a fair preponderance of the evidence", a credible and tangible danger to their health.¹⁹

The argument against public water fluoridation from a constitutional viewpoint is that dental caries are neither communicable nor contagious, and that those most at risk can receive treatment through less invasive and more discreetly targeted means. Opponents claim that as water fluoridation benefits mainly children under 9-12 years of age, it is not really an intervention to serve general public health, and a majority do not benefit from mandatory water fluoridation. It is also feared that fluoride may have adverse health effects on the general public, which outweighs the potential benefits in reduced dental caries in children.

The US Supreme Court has never decided whether water fluoridation is a valid exercise of the right of state police power or as opponents claim, a violation of the constitutional right of individual citizens to refuse medical treatment.²⁰ To date, fluoridation of public water systems has always been upheld as a valid exercise of state police power in the lower courts. This stems from the application of the "rational basis" test of judicial review to fluoridation laws by all of the appellate courts, as discussed above. The rational basis test is the least demanding form of judicial review, requiring that the goals sought be legitimate, the legislation cannot be arbitrary, and that the means chosen to attain the goals are rational.²¹

¹⁶ Graham & Morin, 1999; Dental Didactics, 1999; Brisbane, 1997; Balog, 1997

¹⁷ McColl v. Strathclyde Regional Council, 1983

¹⁸ Brisbane Taskforce, 1997

¹⁹ Graham & Morin, 1999

²⁰ Balog, 1997

²¹ Balog, 1977

Challenges made on the basis that the benefits are mainly aimed at a minority (namely at children), have been dismissed because the US Supreme Court has held that police power may be applied to a reasonable classification, such as children. Several courts have also held that as today's children are tomorrow's adults, fluoridation passes the rational basis test.

Numerous lawsuits have been filed, none upheld, partly because the courts demand only the standard of "rational basis". This requires the government to prove that worthy or legitimate goals were being sought by the practice of fluoridation and that the means employed were reasonably related to the successful meeting of these goals. The courts assume that any legislation (such as a statute mandating fluoridation) is constitutional unless proven otherwise. Opponents want the "strict scrutiny" standard of judicial review to be applied to water fluoridation: determining if a law is depriving or infringing upon a fundamental constitutional right or freedom; namely that of refusing unwanted medical treatment where an individual with a specific disease poses no threat to the general public. This right has been upheld in 2 distinct findings²², but has not yet been used in the lower courts reviewing anti-fluoridation cases. A strict scrutiny standard requires that the state have a "compelling interest" to enact legislation, and that such legislation be narrowly tailored to achieve its purpose so as not to infringe on personal liberty interests protected by the Constitution. A "compelling interest" is one which the state is forced or obliged to protect, such as preventing the outbreak of contagious diseases. Because tooth decay is not contagious; water fluoridation is not narrowly tailored, and reasonable alternatives exist, opponents believe that fluoridation statutes will fail the strict scrutiny test, and be found to be unconstitutional.

There have been a few note-worthy judgments against water fluoridation. In one case, the fluoridation statute was found to be "unreasonable" because "a prima facie case had been made that fluoridation exposes the population to a tangible risk, albeit uncertain in extent, of unhealthy side effects, and that no" credible and reputable" evidence has been given to justify the intrusion"²³. In the Houston case of 1982, both counsel and witnesses conceded that a rational controversy exists over the effectiveness and safety of fluoridation.²⁴

The Supreme Court has held that "the constitution does not protect an individual 'against all intrusions' but only 'against intrusions which are not justified in the circumstances, or which are made in an improper manner'."²⁵ The zone of privacy protected by the U.S. Constitution is therefore narrow and subject to limitations. Some states have found that public water fluoridation falls within this zone of privacy. The trial court in *Chapman v. City of Shreveport* concluded that fluoridation of the city water supply was not reasonably related to the public health, and that tooth decay is not a matter of public health. Furthermore, it held that the choice to consume fluoride is strictly "within the realm of private dental health and hygiene," and that every person should be free to choose his medical treatment for himself and his family. In another case, the judge found that only the emergency of a present danger justifies quarantine or compulsory treatment. Any proposed health regulation must not impair essential rights and principles, and anyone who wants or needs fluorine can get a prescription for topical application, or consume it in other ways. The judge found that while dental caries is a common disease, it does not endanger the public health, and therefore the prevention of dental caries fell outside of the scope of valid exercise of police power. He believed that education was a better way of spreading the benefits of fluoride than compulsion.

²² Dental Didactics, 1999

²³ The injunction was however stayed by the Illinois Supreme Court on the grounds that the plaintiff had failed to prove an unreasonable exercise of police power. (Graham & Morin, 1999)

²⁴ Graham & Morin, 1999

²⁵ Balog, 1997

6.3 South African legal and policy context

6.3.1 Health Act of 1977

According to Chapter V of the Health Act of 1977, which provides for measures for the promotion of health in South Africa, the Minister of Health has the power to make regulations on a range of matters. Section 37 is headed "Regulations relating to water intended for human use and food processing". The section reads in part –

"The Minister [of Health] may, after consultation with the Minister of Water Affairs, Forestry and Environmental Conservation ... make, in respect of water intended for human use or food processing, regulations relating to – ...the approval, control, regulation, restriction or prohibition of the construction of water purification works, the application of water purification or treatment processes and the addition of any substances to such water for the purpose of its purification or with a view to the promotion of health, and to the furnishing of information relating to such substances" [emphasis added].

Parliament has therefore given the Minister of Health the power in terms of section 37 of the Health Act to make regulations relating to the addition of substances to water not only for the purpose of purification, but also with a view to promoting health. Enacting regulations requiring the addition of fluoride to drinking water for the purpose of reducing dental decay clearly falls within the powers given to the Minister.

6.3.2 Water Services Act of 1997 & National Water Act of 1998

In terms of the National Water Act, the Department of Water Affairs & Forestry (DWAF) is responsible for protecting South Africa's water resources for future generations. DWAF also has a regulatory role in terms of the Water Services Act to ensure that the objectives of the Act, such as access to basic services, are achieved by all Water Service Institutions. The Water Services Act requires all Water Services Authorities to develop Water Service Development Plans (WSDPs) as part of the IDP. Plans to fluoridate must now be part of these plans, and as such must be communicated to the consumers within that municipality.

DWAF's overarching responsibilities are to:

- Protect the aquatic resources for future generations;
- Ensure sustainable water services to all South Africans;
- Support other spheres in the spirit of co-operative government

According to section 9(1) of the Water Services Act:

"The Minister may, from time to time, prescribe compulsory national standards relating to –

(a) the provision of water services;

(b) the quality of water taken from or discharged into any water services or water resource system".

WSA's are required to monitor the performance of WSP's to ensure that standards prescribed under Sect 9 are complied with. Clarity is required as to the responsibility of the WSA vs the WSP with regard to water fluoridation.

According to the Minister, DWAF has committed to ensuring that the process of water fluoridation "is affordable to the end consumer, does not slow down our programmes to extend access to free basic water and does not raise the fluoride levels in rivers downstream of major urban centres to unacceptable levels."²⁶

²⁶ Kasrils R, 2002-6-12, in a speech to Parliament.

6.3.3 Municipal Systems Act 32 of 2000 & Municipal Structures Act of 1998

According to section 4(2) of the Municipal Systems Act, a municipal council *“has a duty toconsult the local community about –*

(i) the level, quality, range and impact of municipal services provided by the municipality, either directly or through another service provider.”

This accords with the requirement in the Fluoridation Regulations for municipalities to inform their consumers about water fluoridation. However it remains unclear exactly what it means to “consult the local community”.

The Fluoridation Regulations are in line with Section 108 of the Systems Act, which provides for Cabinet Ministers to establish national and minimum standards in relation to a municipal service falling within their functional area, in this case Health and Water Affairs.

Under subsection 5, the relevant Cabinet member must -

“(a) take into account the capacity of municipalities to comply with those standards; and

(b) differentiate between different kinds of municipalities according to their respective capacities.” The

Regulations do allow for an exemption in the event of resource constraints, be it in terms of staff, equipment or finances (see Section 6.3.4.1). The recent decision to introduce water fluoridation initially only in the larger urban areas is supported by this clause.

Under the Municipal Structures Act, District Municipalities were allocated the function of administering “potable water supply systems”.²⁷ While they are responsible for ensuring that water supply systems function properly, any decisions regarding national water quality standards are legally the function of the Ministers of Health and Water Affairs, and not of individual municipal councils.

6.3.4 Fluoridation Regulations of 2000

The Regulations on Fluoridation of Water Supplies were gazetted in September 2000, in terms of the 1977 Health Act. Under the regulations all Water Service Providers (WSPs) in the country, (defined as any drinking-water treatment authority, body or organisation supplying drinking water from its treatment facility) are obliged to provide fluoridated water, unless supplied with written exemption by the Director-General of the Department of Health. The possible grounds for exemption are discussed further below.

All WSP's are required to register their water works sites with the Department of Health within 12 months of the regulations, i.e. by September 2001, and implement water fluoridation at sites within 2 years of registration by the Department of Health. They must supply the required technical information, and apply either to register to fluoridate their water supplies, or to apply for exemption under the grounds mentioned in the regulations.

If the WSP is not itself a WSA, then it must enter into an agreement with the WSA whose population is supplied by the WSP.

6.3.4.1 Grounds for exemption

Should a WSP apply for exemption, it may be granted on the following grounds, from Annex D of the Regulations.

²⁷ Section 84(1)(b)

“The water:

- If the raw water available to a supplier already contains the optimum concentration of fluoride as defined in the regulations, or more, then fluoridation is unnecessary and should not be undertaken.
- If the raw water available to a supplier is available intermittently only, then reliable fluoridation can be problematic and should not be undertaken.
- If it is demonstrated that fluoridation of a water supply will have unacceptable impacts on those water resources which receive effluent or diffuse discharges originating from the fluoridated supplies, exemption or termination should be approved.

The community:

- A community may have limited experience of dental decay and therefore, so long as this remains the case, there is no need for fluoridation.

Specific resources:

- Staff - Properly trained staff are vital to the success of fluoridation. Until such staff are appointed, temporary exemption from the implementation of fluoridation should be granted.
- Equipment - Fluoridation requires accurate and well maintained equipment. Until such equipment is available, temporary exemption from the implementation of fluoridation should be granted.
- Chemicals - Specific chemicals in appropriate quantities are needed on a continuing basis for successful fluoridation. Until such chemicals are available, temporary exemption from the implementation of fluoridation should be granted.
- Finance - The water provider must finance the water fluoridation plant, and the users of drinking water must finance the bill for operating the water fluoridation plant. Until such finances are available, temporary exemption from the implementation of fluoridation should be granted.”

Any applications for exemption must be approved in consultation with the DG of DWAF, if DWAF believes that there would be an unacceptable impact on the water resources.

The Regulations do not make provision for municipalities to “opt out” of fluoridation because a municipal council and/or its citizens do not wish to fluoridate. Questions have been raised as to the constitutionality of not allowing individual municipalities to determine for themselves whether or not they wish to practice fluoridation.²⁸ However, according to Schedule 4B of the constitution, local government is responsible for “water and sanitation services limited to *potable water supply systems* and domestic waste-water and sewage disposal systems” (emphasis added). The Draft Water Services White Paper has defined water supply services as: “*the abstraction from a water resource, conveyance, treatment, storage and distribution of potable water, water intended to be converted to potable water and water for industrial or other use, where such water is provided by or on behalf of a water services authority, to consumers or other water services providers. This includes all the organisational arrangements necessary to ensure its provision including, amongst others, appropriate health, hygiene and water-related awareness, the measurement of consumption and the associated billing, collection of revenue and consumer care.*”²⁹

According to the 1996 Constitution, health is a concurrent national and provincial function, with local government responsible for “municipal health services”. According to a recent Cabinet decision³⁰, municipal health has been defined as “environmental health services”.³¹ Environmental health generally entails the enforcement of food-safety and hygiene regulations. Decisions regarding measures intended to promote health therefore clearly fall outside the powers of municipalities.

The decision to add fluoride to drinking water with the aim of promoting health clearly falls outside the scope of the local government function, as already mentioned above. There is therefore no basis on which to argue that the national Fluoride Regulations intrude on a matter which falls within the legislative authority of

²⁸ See footnote 2 above for an explanation of the Irish decision to have mandatory rather than enabling legislation.

²⁹ DWAF, 2003

³⁰ Cabinet announcement, 7 November 2002

³¹ All other primary health care services – preventative, promotive and curative services, will be regarded as a provincial competence.

municipalities. It is not open to a municipal council to refuse to implement the Regulations because that is what the majority of its citizens want.

6.3.4.2 Considering applications to implement fluoridation

When considering applications by a WSP to implement water fluoridation, the regulations require the D-G of Health to consider the following information:

- Dental caries experience in the supply area of the water provider;
- the population size in the supply area of the water provider;
- the estimated per capita costs of fluoridation in the supply area of the water provider;
- the feasibility of using alternative fluoride supplements; and
- the information required in Annex A of the regulations. This includes the volume of water supplied each month, the local authorities supplied with water, the sources of raw water and comments received from the public.

The D-G is obliged to consult with the D-G of DWAF to assess the potential impact on water resources. Should the D-G of Water Affairs and Forestry be of the opinion that there may be an unacceptable impact on these water resources, the D-G of Health may require the water provider to carry out an assessment of this impact, to be evaluated by the D-G's of both Health and DWAF.

DWAF is required to evaluate all applications to determine the impact on the water resources. For example, the presence of up-stream fluoridation may remove the need to fluoridate water within a particular municipality. DWAF must also assess the respective institution to ensure that the objectives of the Water Services Act will be met. Only after DWAF has recommended an application, can a WSP register with the DOH to fluoridate their water supplies.

The DWAF guidelines for evaluating applications

In addition to the Regulations, the DWAF has developed a protocol to be followed to evaluate applications to fluoridate water supplies. In terms of this protocol, when evaluating individual applications to fluoridate water supplies:

The impact on the environment will be assessed;

DWAF insisted that the Regulations contain a clause that allowed for an impact assessment in cases where one was deemed necessary. There are 3 possible scenarios:

- Where the waste water after domestic use is discharged directly to the sea, there is no impact on the water resources, and the department would favourably consider such applications;
- Where the waste water is discharged into catchments where studies have shown that downstream fluoride levels are already above acceptable levels or fluoridation would raise the fluoride level above that acceptable for human consumption;
- OR inland resources where the fluoride level is yet to be established, DWAF will require impact assessments to be done.

The application will only be considered in terms of the principles of the Water Services Act, if no negative impact on service provision is evident;

In terms of the impact on service provision, DWAF will consider the following:

- Whether all citizens supplied by the WSP have access to at least basic services – if a portion of the community does not have access to a basic water supply, and the cost of fluoridating the water will significantly delay the extension of such services, the department will advise that the water not be fluoridated at this stage.
- Whether the requirement to fluoridate the water will adversely affect the WSA's ability to supply free basic water to consumers. Should a significant adverse effect be indicated, the DWAF will advise that the water not be fluoridated until free basic water becomes a reality.
- Whether the WSP has the capacity to operate the service satisfactorily. Smaller operators often do not have sufficient qualified staff to e.g. guarantee the safe operation of fluoride dosing equipment and therefore **initially only plants serving more than 100 000 people** will be recommended to practice fluoridation. (emphasis added)

DWAF's decision and recommendations will then be forwarded to the DOH.

Source: Presentation to National Portfolio Committee, 12 June 2002

6.3.4.3 Current Issues regarding the approval of applications and exemptions

The Regulations require co-operation between the DOH and DWAF on processing applications. There is a need for greater clarity on the hierarchy of conflicting protocols for considering applications, for example according to the DWAF guidelines, areas with populations served by smaller treatment works (under 100 000 people per works) will not "initially" be considered for fluoridation. It is unclear how long this limitation will apply, or if there will be a lower limit in the future.³² The Department of Health has settled on a cut-off of 60 000 people.

There is also a need for greater transparency on exactly how applications will be assessed, how public opinion will be taken into account, how lack of financing for water service providers will be addressed, and how capacity to implement fluoridation will be measured.

Greater clarity is required on the actual minimum requirements for the safe implementation of water fluoridation: what is the minimum level of skills and personnel required and below what scale of operations is water fluoridation no longer cost-effective, taking both capital and operating (including labour) costs into account?

³² The MRC report suggested that as the capital costs of water fluoridation were sensitive to economies of scale, water fluoridation should be targeted at water supply schemes covering around 200,000 residents.

6.3.4.4 Notice and comment provisions

The regulations require that the WSP inform the local authority on behalf of which they supply water, who in turn must give the public the opportunity to make 'substantiated' comments on water fluoridation. These comments must be included with the registration application.

It is unclear what the purpose of the comment procedure is. The Regulations do not direct the D-G or anyone else to take account of the comments received at any stage. The D-G is not empowered to take the comments into account when he or she considers whether or not to grant an exemption from the obligation to fluoridate, but must use the criteria set out in Annexure D to the Regulations. Those criteria include, in relation to a community, that community's experience of dental decay, but not the community's views on fluoridation. The section on the comment procedure is perhaps pointless, but not susceptible to legal challenge. At worst, they are misleading in that they claim to offer the public a say in the proposed practice of fluoridation.

6.3.4.5 The issue of defluoridation, and any obligation on WSP's to reduce fluoride levels

It has been suggested that, because the aim of the Fluoride Regulations is to achieve the optimum concentration of fluoride in drinking water throughout South Africa, areas where the fluoride level is higher than 1.0 mg per litre – for example areas in the Northern Cape – will effectively be under an obligation to remove fluoride from drinking water, which is an expensive process.

However there is no such obligation in the Regulations. "Fluoridation" is defined in the Regulations as "*to adjust the fluoride concentration of a water supply by the addition of a fluoride compound to obtain an optimal fluoride concentration*" (emphasis added). The obligation to practice fluoridation currently only involves the addition of fluoride, not the subtraction of fluoride.

It is recommended that the issue of defluoridation be investigated further, especially with regard to possible obligation on WSP's to reduce excessive fluoride levels. This could have significant financial implications for the municipalities concerned.

6.3.4.6 Legal liability

It is possible that legal claims will arise as a consequence of the implementation of the Regulations. This could be either as a consequence of the Regulations properly implemented (for example consumption of properly fluoridated water causing severe dental fluorosis) or as a consequence of the Regulations being implemented incorrectly (for example fluoride well in excess of the stipulated amount being added to water). In regard to claims made where the Regulations were implemented incorrectly, the claim would ordinarily be made against whoever was at fault: i.e. whichever WSP made the mistake of adding too much fluoride.

Claims which arise as the result of implementation of the Regulations as they are supposed to be implemented, rather than as the result of a mistake, for example a class action by a group of people who suffering from kidney disease who can show that the ingestion of fluoride from fluoridated drinking water has led to their contracting other forms of sickness, should be brought against the Health Minister. In order to bring a damages claim against the Health Minister, they would need to prove that the regulations were made in negligent disregard of the risks of fluoridation. Negligence could arise either through a failure to give proper consideration to known risks associated with fluoridation, or through a failure to do proper research into the possible risks of fluoridation. The claim would be against the Health Minister in his or her capacity

as minister; a claim would therefore lie against future Ministers of Health in their capacities as minister, and not only against the current Minister.

6.3.5 Fluoridation and the Bill of Rights: Possible Challenges under the Constitution

If legislative acts of government, such as the Fluoridation Regulations, are found to violate the fundamental rights protected by the Constitution, they can be declared invalid on the basis that they are unconstitutional.

Any Bill of Rights based challenges to water fluoridation will be analysed in two stages. In the first stage, the court will consider whether the act under consideration infringes on a constitutionally protected right or freedom. This requires not only identifying the relevant right, but also defining the extent of that right. If the court decides that the act does infringe a constitutionally protected right, the enquiry then moves on to the second stage of establishing whether the infringement is a permissible one. The test for this is set out in the Constitution's "limitations clause" in Section 36, which permits an infringement (or "limitation") if it is "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all factors ...".

As in the international debate, opponents of fluoridation see the mandatory fluoridation of drinking water as the primary alleged infringement. Evidence from medical and scientific experts on the benefits and harms of water fluoridation would be critical in constitutional litigation on the issue. In the first stage of the enquiry, opponents of fluoridation would have to prove to the court, on a balance of probabilities, that there is in fact an infringement. If the case progresses to the second stage, the Minister of Health would have to satisfy the court that the infringement is justified.

6.3.5.1 The right to bodily integrity

Section 12 of the Constitution reads –

"(2) Everyone has the right to bodily and psychological integrity, which includes the right – ... (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent."

Section 12 entrenches the right to freedom and security of the person, and section 12(2)(b) offers the strongest Bill of Rights argument against fluoridation. It is a freedom right, i.e. the right to be left alone, the right not to be interfered with. Water fluoridation is a good example of a subtle form of bodily invasion, or interference, by the state. Challengers of water fluoridation would have to satisfy the court that this right protects people against subtle forms of bodily interference and that water fluoridation infringes that right. There are a number of issues which could be raised with regard to the factual arguments. The right to bodily self-determination must include the right to choose whether or not to use a substance which, by definition, has an effect on one's body. Administering fluoride by means of drinking water amounts to imposed medication with an uncontrolled dosage and therefore infringes the right. It is expensive for individual consumers to "opt out" of consuming fluoridated water and practically impossible to opt out completely, due to the use of fluoridated water in other foodstuffs.

A second, but weaker, potential right is section 12(2)(c), the right "not to be subjected to medical or scientific experiments without [a person's] informed consent". Identifying a medical or scientific experiment is not necessarily easy. Fluoridation supporters may view the "experiment" label as polemical and emotive. Even opponents of fluoridation may be reluctant to go down the medical or scientific experiment road; they may feel more comfortable arguing that the research has now been done and shows on balance that the risks of fluoridation outweigh its benefits. However the decision to implement water fluoridation initially on a

frontrunner basis in 5-7 municipalities could add weight to claims of “experimentation”, especially with statements in the press alleging that the frontrunners will be used to “gauge the effects” of water fluoridation³³. Care must be taken to explain the purpose of the frontrunner process – is it to generate lessons for wider implementation of water fluoridation, or is to assess the health benefits of water fluoridation?³⁴

From a legal perspective, the burden would again be on a person challenging the Fluoride Regulations to persuade the court that fluoridation of water infringes this right. Expert evidence would probably be needed on what constitutes a medical or scientific experiment.

If the challengers satisfy the court that the Regulations infringe section 12(2)(b) of the Constitution, the Minister would then be required to prove that the infringement was justified under the limitations clause. The limitations clause (section 36 of the Constitution) reads:

“(1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including –

- (a) the nature of the right;*
- (b) the importance of the purpose of the limitation;*
- (c) the nature and extent of the limitation;*
- (d) the relationship between the limitation and its purpose; and*
- (e) less restrictive means to achieve the purpose.”*

The purpose of the limitation here is the promotion of health, specifically dental health. Although opponents of fluoridation may argue that preventing dental health is less important than some other public and primary health care goals (such as controlling the spread of HIV and AIDS), it is likely that a court would accept that the promotion of health is critically important in “an open and democratic society based on human dignity, equality and freedom”. The Minister’s arguments would be supported by other rights entrenched in the Bill of Rights, such as Section 27 which entrenches the right to access to basic health care services and places an obligation on the state to “*take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation*” of that right. The Minister may argue that preventative dental care is included under the definition of basic health care services.

The expert evidence of both sides would be critical in proving if water fluoridation is rationally connected to the purpose of improving dental health. As noted elsewhere, there is a great deal of disagreement between medical and scientific experts on this issue. As the state’s objective in fluoridating water is not simply promoting health, but promoting dental health in an equitable way, more nuanced evidence would be relevant. Opponents of fluoridation may argue that many poor areas in South Africa do not receive piped water and that fluoridation therefore cannot achieve the objective of the equitable promotion of health. However a court may well dismiss this as a “dog-in-the-manger” argument³⁵.

Expert evidence would again be required on whether there are any less restrictive means (ie methods which infringe less on the right) available to the Minister to achieve the same purpose, such as primary school programmes where children, under the supervision of their teachers, brush their teeth twice daily with

³³ SALGA quoted in the Mercury, November 14 2002.

³⁴ Some articles have described the pilots as “frontrunners in testing the *effectiveness* of fluoridation in the water supply” (Davies, 2002) while others have indicated that the frontrunner process “will enable the generation of lessons, to inform subsequent implementation in other areas.” (Mercury, 2002)

³⁵ This alludes to a fable where a miserly dog will not give the cow access to the hay in the manger, even though he does not want it himself.

fluoride toothpaste. Opponents of fluoridation may argue that this is both a less restrictive and more effective method than fluoridation of promoting dental health.

The courts essentially treat the issue of the nature and extent of the limitation as a cost - benefit analysis. Assuming that the Minister has shown the court that the Fluoride Regulations serve an important purpose, that they are rationally connected to the improvement of dental health and that they employ one of the least restrictive methods available to achieve their purpose, the court then enquires whether the Regulations nonetheless impose costs on the holders of the infringed right which outweigh the benefits which the infringement confers on other members of society. The values of openness, democracy, human dignity, equality and freedom will inform this balancing act. Again, expert evidence will be critical here, particularly on the health risks associated with fluoridation, both generally and to particularly vulnerable groups.

6.3.5.2 The environmental right

If it can be shown that fluoridation damages the environment, for example that the discharge of fluoride into waterways affects freshwater and marine plant life, then the Regulations can be challenged on the basis that they infringe section 24 of the Constitution. Section 24 reads:

*"Everyone has the right –
to an environment that is not harmful to their health or well-being; and
to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that –*

- *prevent pollution and ecological degradation;*
- *promote conservation; and*
- *secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development."*

Again, evidence on the facts would be critical in litigation. Much of the limitation analysis argument would in all likelihood take place in relation to the cost versus benefit enquiry raised by "the nature and extent of the limitation". If the evidence shows that, on the one hand, fluoridation harms the environment and, on the other hand, fluoridation improves dental health, the court may have to balance two competing constitutionally protected rights.

6.3.5.3 A right to fluoride?

The effectiveness of the Regulations depends on communities receiving piped water: areas which do not have a piped water supply will not receive fluoridated water. It is possible that communities in such areas could construct an argument to the effect that the state is obliged to provide them with fluoride – if not by laying water pipes, then by making some other method of fluoride treatment available, such as topical fluoride rinses or toothpastes. The argument would be based on the Section 27 right to access to health care services mentioned above and backed up by the right to equality entrenched in section 9 of the Constitution. Section 9 reads: *"Everyone is equal before the law and has the right to equal protection and benefit of the law. Equality includes the full and equal enjoyment of all rights and freedoms"*.

This kind of rights argument would amount to a demand for the provision of certain services or facilities from the state, rather than a challenge to the Regulations. In essence, the applicants would be saying that the right to health care services includes the right to treatment aimed at preventing tooth decay; that the state has recognised that right and has promulgated the Regulations in order to promote the right; that the

Regulations do not achieve the right because they depend on universal piped water and therefore discriminate unfairly between citizens with access to piped water and citizens without such access; and that the state must remedy the situation either by laying more water pipes or by some other means. The Regulations would thus be used as evidence of the state's commitment to the provision of fluoride to all citizens in the country.

It should be pointed out that, traditionally, it is very difficult to persuade a court to make an order which has direct implications for how a government spends its budget. As has been mentioned above, section 27, which entrenches the right to health care, places an obligation on the state to *"take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation"* of that right. A court would no doubt be satisfied if the state can demonstrate that it is taking steps to realise the right progressively and that it has achieved delivery of a certain minimum core obligation with respect to the right. The enactment of the Regulations, coupled with a roll-out plan in respect of laying water pipes, may well satisfy a court in this regard. It is therefore recommended that the Government demonstrate a roll-out plan to provide a reticulated water supply, and the investigation of other sources of fluoride where appropriate.

6.3.6 Was the Power to Make Regulations Exercised Reasonably?

Opponents of fluoridation may argue that, as a fact, fluoridation does not promote health and is instead harmful to health: the Fluoride Regulations therefore will not achieve the *"promotion of health"*. In order for the Minister's exercise of her power to make regulations to be legal from an administrative law perspective, she must have exercised that power reasonably; anyone challenging the Minister's exercise of her power would need to show that she had exercised it unreasonably. Whether or not the fluoridation of water promotes or harms health is a question still greatly contested by scientists and doctors, and a court would be very unwilling to substitute another interpretation of the available medical and scientific evidence for the Minister's interpretation. However although recent, credible reports such as the York Review and MRC report have concluded that fluoridation does reduce dental decay, the extent of such benefit is still debated, and may be negligible

6.3.7 International Conventions

There are few international conventions dealing with human rights which contain provisions potentially relevant to the fluoridation argument. Of those, South Africa has not acceded to the Council of Europe's "Convention for the Protection of Human Rights and Dignity of the Human Beings with Regard to the Application of Biology and Medicine: Convention of human rights and biomedicine 1999".

Article 2 of the Convention of Human Rights and Biomedicine affirms the primacy of the human being over the sole interest of science or society:

"This establishes that the wishes of an individual in respect to his/her exposure to treatment for medical conditions takes precedence over state objectives, although such wishes might be overridden in the case of virulently infectious person being allowed to move freely in public."

Article 5 states that no person may be forced to undergo an intervention without their consent, and must be able to give or refuse their consent to any intervention involving their person. Opponents of fluoridation argue that dental decay is a medical condition, and fluoridation is therefore a preventative medical intervention, which according to the Convention cannot be imposed on the population as a whole without the express consent from every individual of the population. Consent must be based on an understanding of the possible

risks and benefits of fluoridation and its alternatives, including the risks related to the characteristics of each individual, such as age or the existence of other conditions.³⁶

However South Africa is a signatory to the United Nations Convention on the Rights of the Child. Article 24(1) reads –

"[Signatory] parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. [Signatory] parties shall strive to ensure that no child is deprived of his or her right of access to such health care services."

This places an obligation on South Africa to ensure the provision of necessary medical assistance and health care to all children with the emphasis on primary health care, to combat disease and to develop preventive health care.

From the point of view of fluoridation litigation, the provisions of the UN Convention do not really add to the South African Constitution. Whether supporters of fluoridation or anti-fluoridationists are able to rely on the Convention to bolster their arguments will again rely on the quality of their expert evidence.

6.4 Public awareness and education requirements

6.4.1 Public Opinion in South Africa

According to a survey conducted by the Human Sciences Research Council in 1995, as many as 6 out of 10 South African's supported the addition of fluoride to water *if it can reduce tooth decay*, (emphasis added) while only 9% were opposed to the measure³⁷. The 1995 HSRC survey has been widely quoted as proof of public support of water fluoridation. However, according to the DOH, surveys have shown that most people in South Africa do not know what fluoride or water fluoridation is. Only about 25% of South Africans could correctly identify the purpose of water fluoridation.³⁸ In light of this finding, the survey results could perhaps be more correctly interpreted to demonstrate a widespread desire for improved dental health, rather than support for a specific fluoride "vehicle".

The South African Dental Association and the South African Medical Association (SAMA) released a joint statement giving their full support for the implementation of water fluoridation in South Africa" as a cost-effective public health measure to prevent tooth decay." They "are satisfied that there is no valid reason for denying the scientific benefits of water fluoridation to the people of South Africa."³⁹

No surveys could be found as part of this study that establish the views of those who are expected to gain the most – those who currently cannot afford other forms of preventative health care such as brushing with a fluoride toothpaste, and good nutrition. However, it is unlikely that the most disadvantaged sections of the community, both in economic terms and in terms of access to dental care, in the form of education and professionals, will benefit from water fluoridation, due to technical limitations. Water fluoridation (assuming that it is effective) will benefit mainly the urban poor.

Although legally the requirements for public comment were met, levels of awareness regarding water fluoridation remain low. Knowledge of the controversy surrounding water fluoridation seems to be especially poor. A scan of newspaper articles since 1997 found only one press release from the Department of Health,

³⁶ Cross, 2000

³⁷ www.edoc.co.za

³⁸ Chikte et al, 1999

³⁹ SA Medical Association, 2002.

notifying the public of the release of the regulations,⁴⁰ and a recent spate of articles in the press of varying quality.

6.4.2 Public Awareness and Education Required for Successful Implementation

It has been agreed that an intensive campaign is required in addition to water fluoridation in South Africa, to teach people about dental care, with an emphasis on hygiene and nutrition.⁴¹ The role of foods with high sugar content in dental caries needs to be emphasized. The White Paper on Health (1997) sets out a nutrition programme to reduce the level of refined sugars in common foods. UNICEF has also highlighted the importance of improved nutrition as a supplement to fluoridation, while the Berlin Oral Health Declaration maintains that oral health can be maintained as part of an overall “prevention” strategy to restrict sugar consumption and enhance personal hygiene. However, personal hygiene needs clean water. It is therefore essential that the extension of basic water services to all South Africans continues.

In terms of public awareness, the following have been recommended:

- Proper labeling of the levels of both sugar and fluoride in foodstuffs is required.
- The Centre for Disease Control (CDC) in the US has also recommended that people be aware of the concentration of fluoride in their drinking water.
- The CDC has found that the beneficial effects of fluoride are predominantly post-eruptive and topical. They have therefore recommended that all people “drink water with an optimal fluoride concentration *and* brush their teeth twice daily with fluoride toothpaste” (emphasis added),⁴² because *frequent exposure to small amounts of fluoride* each day will best reduce the risk for dental caries in all age groups. Combined use of fluoride toothpaste and fluoridated water offers protection above either used alone.
- Adults should supervise the use of fluoride toothpaste among children under the age of 6.
- Use an alternative source of water for children under the age of 8 years whose primary drinking water contains more than 2 ppm fluoride.

6.4.3 International Recommendations on Required Levels of Public Awareness

The recent MRC report has identified additional information needed by the public in order to make informed decisions with regard to water fluoridation. Their recommendations include improving the public’s understanding about complex health risk/benefit debates through education and better, jargon-free public information. The public needs to be made aware of the inevitability of uncertainty in research findings; an inherent feature of science and medicine, but this is not a concept that is well understood. There is a need to explain the concept of different strengths of evidence that can be derived from different types of research design, as well as the changing methodological standards that have been used in research over time. The concept of different quality of research available in some articles published on the web, as opposed to research published in peer-reviewed scientific journals, also needs to be explained.

Other information that would be useful to communicate to the public about water fluoridation includes:

- the consequences of not preventing dental caries, in terms of costs, tooth decay and other possible consequences such as malnutrition;

⁴⁰ Press Release on 12/6/1998

⁴¹ Professor Chitke, Letter to the Star, 1998.

⁴² CDC, 2001

- the strength of evidence on the problems and benefits of alternatives to water fluoridation;
- and the nature, effects and degree of aesthetic impact of dental fluorosis.⁴³

In light of the ongoing debate over fluoridation, the work of Sandham (1990) on the impact of public “outrage” on the perception of possible health risks and benefits seems particularly pertinent.⁴⁴ Ways need to be found of addressing public concerns, especially through education campaigns, providing information, and acknowledging the latest studies and findings, as well as the ongoing debate. Both preventive benefits and potential harms must be set out clearly and consistently to avoid confusion and mixed messages to the public.

The MRC report indicated that there were several areas where further information could help the public make informed decisions. These included:

- Clarity about the prevalence of different forms and severity of dental fluorosis;
- Clarity on the role of impacts on tooth mineralisation not associated with water fluoridation;
- Aesthetic defects caused by other means, including the over-use of topical products rather than sustained exposure to the low doses found in water;
- Greater understanding is required on the potential harms of fluoridation;
- Better understanding of the public perception of different types of dental fluorosis.

6.4.4 Social Impact of Dental Decay and Fluorosis

Although children are the primary beneficiaries of water fluoridation, improved dental health has important implications for all age groups. Dental decay leads to much suffering and lost work days. Poor oral health and tooth loss can contribute to malnutrition, particularly in the elderly. Oral health is an important part of the daily comfort, hygiene and general health of older adults. Tooth loss can disturb eating, speaking, general appearance and comfort, and can also lead to more serious illnesses.⁴⁵ Poor dentition also affects self-image and personal appearance, and decreases general life satisfaction.⁴⁶

The view of fluorosis as a minor cosmetic effect should be viewed against a study of the psychosocial impact of fluorosis, which found that people were as likely to seek treatment for fluorosis, as for overcrowding and overbite.⁴⁷ There is general agreement that the current scientific literature is weak on perceptions regarding fluorosis, and that more high-quality scientific research needs to be carried out⁴⁸

6.5 Social feasibility

6.5.1 The Intended Beneficiaries in a South African Context

The approach to oral health in South Africa remains largely curative, and is delivered at an individual level. In SA, over 75% of the black population reported visiting the dentist or dental clinics for symptomatic, as opposed to preventative, reasons.⁴⁹ Most oral health care service delivery is dependent on sophisticated and expensive technology, and the training of dental personnel takes place at six dental schools which are

⁴³ MRC, 2002

⁴⁴ MRC, 2002

⁴⁵ Reisine, cited in Dharamsi, 2002.

⁴⁶ University of new England, School of Health

⁴⁷ Cohen, 2001: 579

⁴⁸ McNally & Downie in response to Cohen, 2001.

⁴⁹ Van Wyk, Faber, Van Rooy & Olivier 1994 cited in Dharamsi et al, 2002.

located in or near the major metropolitan areas of the three most affluent provinces in the country.⁵⁰ Many South Africans, particularly those living in rural areas, are therefore currently denied access to adequate dental health care and trained staff.

Tooth decay is the most common chronic disease known to human kind. About 60% of all 6-year old children in South Africa have dental caries,⁵¹ which is above the goal set by the Department of Health in 1994 for 50% of 6 year olds to be caries-free by 2000. According to the DOH “tooth decay is at unacceptably high level in certain communities in South Africa, and it is likely that these levels will increase especially amongst the poor.” However according to a recent national dental survey, the DMFT of 1.05 for 12-year-old children and 1.86 for 15-year-old children is regarded as low in terms of the WHO classification for dental caries for these age groups.

The greatest benefit of water fluoridation is expected to be for children, in particular those children from poor and increasingly urbanised communities. Water fluoridation is intended to “transcend the barriers of class and race and so will (level) out the differences in dental health which normally separate children from better-off and poorer backgrounds.”⁵² Fluoridation is therefore expected to contribute to equity in health and the building of a healthy nation.

Water fluoridation is intended to benefit everyone, but in particular the lower income groups, who have the highest incidence of dental caries, and who cannot afford to purchase fluoridated toothpaste or other dental services.⁵³

6.5.2 Will Water Fluoridation Benefit the Intended Beneficiaries in South Africa?

Poor South African's are expected to benefit most from reduced dental caries in the event of water fluoridation. Concerns have been raised by organizations such as Rand Water that, “given that most people in rural areas do not receive piped water the benefit will not reach (certain portions of) the target population.”⁵⁴ However, the prevalence of dental caries appears to be higher among the urban population,⁵⁵ according to recent national oral health surveys.

Many people will not receive water fluoridation in the short term due to technical and capacity constraints. This is supported by the current DOH cut-off limiting fluoridation to treatment works serving more than 60 000 people. It is not known if this limit will drop in the future, or to what level. For the moment however, it is likely that a significant number of the intended beneficiaries (the 7 million unserved, plus approximately 3 million served by schemes serving less than 60 000) will be excluded from water fluoridation in the short to medium term. It is likely that the overwhelming majority of these people will be poor.

It therefore appears likely that certain sections of the rural population will not be served by fluoridated water. It is unclear what the Department of Health's responsibility will be to these people. The possible grounds for legal challenge from those excluded from fluoridation has been discussed above. In keeping with the principle of reducing oral disease through the “*promotion of health, prevention of oral diseases and provision of basic curative and rehabilitative oral health services*”⁵⁶, the Health White Paper (1997) mentions alternative methods of fluoridation in addition to water fluoridation, such as the use of tooth-brushing

⁵⁰ Chikte, 1998

⁵¹ Van Wyk, 2003

⁵² Department of Health, 1998

⁵³ www.edoc.co.za

⁵⁴ Holtzhauzen, 2002

⁵⁵ Dr Johan Smit & Prof du Plessis, pers comm. 2003.

⁵⁶ White Paper on Health, 1997

schemes at schools. Other methods include fluoridated milk and salt, while the possibility of fluoridated maize-meal has been widely raised.

It is recommended that the Department investigate the possibility of using other forms of fluoride in areas which will not receive fluoridated water, in conjunction with education campaigns in order to improve oral health amongst *all* South Africans.

6.5.3 Water Fluoridation and Social Equality

The 2 main factors affecting dental decay are diet and the use of fluoride products, especially toothpaste. It is widely agreed that tooth decay in children is related to social class,⁵⁷ with dental caries being more prevalent in deprived social groups than in more affluent social groups, especially in the case of young children. Water fluoridation is therefore generally seen as an equitable way of ensuring that everyone in the community, regardless of income or education level, benefits from fluoride.

The York Review examined fifteen studies published between 1969 and 1999 in order to assess the relationship between water fluoridation, dental caries and social class in England. Although the number of studies was small and the quality of evidence was poor, the York Review did find some evidence that water fluoridation reduces inequalities in dental health across the social classes in 5 and 12 year old children, with two UK studies indicating that children from more deprived areas experienced greater reductions in dental caries with water fluoridation than those from more affluent areas. The Review suggested caution in interpreting the results because of the small quantity of studies, differences between the studies, and their low quality rating. The York Review concluded that the research evidence is of insufficient quality to allow confident statements about whether there is an impact on social inequalities.

The MRC report concluded that overall the evidence supports the view that water fluoridation reduces dental caries inequalities between higher and lower socio-economic groups; in no study did water fluoridation increase inequalities. It provides benefits for everyone, but the effects are greater for lower socio-economic groups, particularly in the primary dentition. However, the magnitude of this effect is more pronounced in the deciduous dentition and is generally small.⁵⁸

Therefore while the balance of evidence overall suggests that water fluoridation does reduce caries experience, the magnitude of the effect is subject to a degree of uncertainty but is unlikely to be large in absolute terms. The few studies that have assessed rates of dental decay in communities where fluoridation has been discontinued do not suggest that dental decay increases to any significant degree.

The MRC has recommended that further research be conducted into the following areas: The MRC has recommended that further research be conducted into the following areas:

- the effects of water fluoridation on children aged 3-15 years, and the effect of water fluoridation by social class;
- the impact of fluoridation on quality of life and economic indices in addition to the more customary outcome measures based on the prevalence of decayed, missing and filled teeth;
- the public's perception of dental fluorosis, with particular attention on the distinction between acceptable and aesthetically unacceptable fluorosis;

⁵⁷ MRC, 2002

⁵⁸ Locker, in MRC 2002

- appropriate measures of social inequalities in relation to water fluoridation, dental caries, dental fluorosis and the role of confounding factors such as tooth brushing with fluoride toothpaste, other fluoride therapeutic agents, non-water dietary fluoride ingestion and sugar consumption.⁵⁹

In a developed country context, the majority of the research conducted to date indicates that water fluoridation does reduce dental caries inequalities between high and low social groups. However there is evidence that this trend varies between *developed and developing nations*. While higher caries experience in more deprived communities is a common finding in developed countries, this is not so in less well-developed countries. Studies in West Africa⁶⁰ have found that children from more affluent families tend to experience greater tooth decay, most probably due to increased sugar consumption, while in the UAE, “dental caries experience of children was positively related to parental income, but negatively related to parental education.”⁶¹ Other studies have indicated that levels of dental health are more related to socio-economic factors than to water fluoridation.⁶²

In a recent national dental survey in South Africa⁶³, the incidence of dental caries was found to be significantly higher in the Western Cape (1.99 DMFT for 12 year olds), one of the wealthiest provinces. This is significantly higher than the MDFT of 0.34 for 12 year olds in Limpopo Province. This raises interesting questions into the pattern of dental decay in South Africa.

It is therefore recommended that research in South Africa be conducted in order to determine the relationship between socio-economic class, diet and oral health, particularly between rural and urban communities.

6.6 Conclusions

The Fluoride Regulations were lawfully made, in full accordance with the way in which powers and functions have been allocated between the 3 spheres of government under the Constitution.

Under the Municipal Structures Act, District Municipalities were allocated the function of administering “potable water supply systems”.⁶⁴ While they are responsible for ensuring that water supply systems function properly, whether operated by themselves or by a Water Provider, any decisions regarding national and minimum water quality standards are legally the function of the Ministers of Health and Water Affairs⁶⁵, and not of the individual municipal councils or Water Authority.

The outcome of any constitutional challenges will therefore depend on the strength of expert evidence, and the persuasiveness of the argument put forward by opponents to fluoridation.

Legal liability will depend on the nature of the claim. Claims for the improper implementation of the regulations will be against the relevant Water Service Authority, while claims against fluoridation itself will be against the Minister of Health.

⁵⁹ MRC, 2002

⁶⁰ Olojugba & Lennon, 1990 in MRC 2002

⁶¹ Al-Hosani & Rugg-Gunn, 1998, in MRC, 2002

⁶² Colquhoun in MRC, 2002

⁶³ Van Wyk, 2003

⁶⁴ Section 84(1)(b)

⁶⁵ Municipal Systems Act of 2000

Defluoridation of water supplies where natural levels exceed the recommended level of 0.7 ppm is not required by the regulations. The responsibility of WSPs with natural fluoride levels above the recommended level needs to be clarified.

Although the regulations are aimed at reducing the incidence of dental caries, particularly in poorer communities, many rural communities will in all likelihood never benefit from water fluoridation, due to technical constraints both in the short and the long term. Alternative measures of improving access to dental services, and basic dental care must be implemented for these groups.

There are fears that the cost of introducing water fluoridation will delay efforts to connect poor communities to piped water.⁶⁶ However, DWAF has clearly stated in a presentation to the National Portfolio Committee that the provision of Free Basic Water remains the priority.

6.7 Recommendations

It is recommended that the issue of defluoridation be investigated further, especially with regard to any possible obligation on WSP's to reduce excessive fluoride levels. This could have significant financial implications for the municipalities concerned.

For those sections of the population who will not receive fluoridated water, it is recommended that the Department of Health investigate the possibility of using other forms of fluoride in conjunction with education campaigns, in order to improve oral health amongst *all* South Africans.

There is a need for greater clarity on the hierarchy of conflicting protocols for considering applications, and the application process. How will capacity to implement fluoridation be measured?

Greater clarity is required on the matter of public comment, and the process to be followed by municipalities when receiving these comments. How will these comments be taken into account?

Further investigation is required into the minimum recommended scheme size for implementing water fluoridation, both economically and technically.

In order to reduce opposition, it may be necessary to clarify the purpose of the frontrunner process – is it intended to generate lessons to support broader implementation of water fluoridation in the near future, or are they longer-term pilots to determine the health effects of water fluoridation?

It is recommended that research in South Africa be conducted in order to determine the relationship between socio-economic class, diet and oral health, particularly between rural and urban communities.

In terms of public awareness, the following have been recommended:

- Proper labeling of the levels of both sugar and fluoride in foodstuffs is required.
- People should be made aware of the concentration of fluoride in their drinking water.
- People should be made aware of the consequences of not preventing tooth decay, in terms of costs, dental caries and other related health effects such as malnutrition from tooth loss.

⁶⁶ Carnie, 2002, www.iol.co.za

- Frequent exposure to small amounts of fluoride should be encouraged, such as drinking fluoridated water *and* brushing with a fluoride toothpaste twice a day.
- Adults should supervise the use of fluoride toothpaste among children under the age of 6.
- Alternative sources of water should be found for children under the age of 8 years whose primary drinking water contains more than 2 ppm fluoride.

Other recommended research includes:

- Clarity about the prevalence of different forms and severity of dental fluorosis;
- Better understanding of the public perception of dental fluorosis
- Better understanding of the potential harms of fluoridation.

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APPENDIX 6A

STATUS OF WATER FLUORIDATION IN VARIOUS COUNTRIES

Where possible to identify, only figures for populations receiving artificially fluoridated water were included. Figures should be seen as indicative only, as it was not possible to verify the data from the various sources.

From the list below, there are currently 28 countries who practice artificial water fluoridation, to varying degrees.

Country	% of population receiving artificially fluoridated water	Notes
Argentina	10%	
Austria	0%	Rejected
Australia	67%	
Belgium	0%	Recently banned? Rejected: experimental treatment plant was discontinued
Brazil	33%-41%	
Brunei		Preparing to commence
Bulgaria		(Disputed status)
Canada	40%-50%	
Chile	37%	
China	0%	Banned – only areas with naturally high levels of fluoride
Columbia	80%	
Costa Rica	?	5 communities, number of people affected unknown
Cyprus	0%	Areas with naturally high levels
Czech Republic	20%	
Cuba	?	Unknown extent
Denmark	0%	Rejected in 1977 due to lack of reliable evidence of effects on humans and the environment
Finland	0%	Stopped in 1991.
Fiji	36%	One community only
France	0%	Rejected in 1980 due to doubts over benefits & health effects. Areas with naturally high levels
Gabon	0%	Areas with naturally high levels
Germany	0%	Abandoned for legal and health reasons.
Greece	0%	(disputed status)
Guatemala	?	1 800 000 people
Guyana	5%	
Hungary	0%	Stopped for technical reasons. Areas with naturally high fluoride levels
Hong Kong	?	Unknown extent
Iceland	0%	
Ireland	70%	
Israel	50%	Mandatory regulations, every settlement with over 5000 residents. Not yet implemented. Should increase to 90%
Italy	0%	disputed status - seems to be one community only, with naturally high fluoride levels
Japan	0%	Rejected. Recently endorsed by government.
Kenya	0%	Areas with naturally high fluoride levels
Korea (Republic of)	?	1.5 million people
Libya	7%	
Luxembourg	0%	
Malaysia	48%	Unknown extent
Mexico	1%	
Namibia	0%	Areas with naturally high fluoride levels
Netherlands	0%	Tried for 10 years. Gave it up for legal and acceptability reasons.
New Zealand	57-67%	
Nigeria	0%	Areas with naturally high fluoride levels
Norway	0%	Rejected. Areas with naturally high fluoride levels

Panama	19%	
Paraguay	?	350 000 people
Papua New Guinea	2%	One community only
Philippines	<1% - 7%	Only US military base?
Poland	0.1- 4%	
Portugal	?	One community only – BFS list says none
Romania	0%	Disputed – apparently only naturally high levels, no artificial fluoridation
Russia	15%	
Senegal	0%	Areas with naturally high fluoride levels
Singapore	? 100%	Unknown extent. 100% according to BFS
South Korea		39 cities fluoridated, 9 installing equipment
Spain	<1-10%	
Sri Lanka	0%	No artificial water fluoridation – only areas with naturally high levels
Sweden	0%	Legislation prepared. Not implemented due to objection of special fluoride commission
Switzerland	4%	Basle only
UK	9%	
US	50% - 70%	
Vietnam	?	Introduced over past 10 years

Sources : ADA, 2002; Irish Forum on Fluoride, 2001; Brisbane Taskforce, 1997; www.fluoridation.com/country.htm; Hileman, 1988; Connett, 2002; British Fluoridation Society, unknown date.

APPENDIX 6B

PERCENTAGE OF POPULATION SERVED BY RURAL SCHEMES

The table below is based on an incomplete data-set from DWAF of rural water supply schemes. Despite the incompleteness of the data, it is apparent that a significant proportion (47%) of the rural population who have been supplied with at least a basic water supply, are served by projects serving less than 50 000 people.

Nationally this amounts to a conservative estimate of approximately 3 million people, of those already served by water schemes, who will not benefit from water fluoridation at least in the near future, due to technical constraints.

Under the current DOH cut-off of 60 000, roughly 3 million people of those already served will not receive fluoridated water.

If it is assumed that future water supply schemes in rural areas follow a similar pattern, (a conservative assumption), then an additional 47 – 62%, or 3.2 – 4.3 million of the remaining unserved 7 million will receive water from smaller schemes.

This amounts to a total of 7 – 8 million people who will possibly not receive fluoridated water in the medium to long term.

	Number of projects	Total population served ('000)	No of projects serving:			Population served ('000) By projects with:			% Population served by projects with:		
			over 100 000 people	50 000 to 100 000 people	less than 50 000	over 100 000 people	50 000 to 100 000 people	less than 50 000	over 100 000 people	50 000 to 100 000 people	less than 50 000
EC	71	572	0	1	70	-	52	520	0%	9%	91%
FS	29	772	2	5	22	311	198	263	40%	26%	34%
KZN	166	1,565	2	3	161	680	91	794	43%	6%	51%
MPM	25	809	1	4	20	187	205	418	23%	25%	52%
NC	35	158	0	0	35	-	-	158	0%	0%	100%
NP	44	1,373	3	6	35	718	218	437	52%	16%	32%
NW	45	1,248	3	6	36	518	215	515	41%	17%	41%
WC	19	124	1	0	18	101	-	23	81%	0%	19%
RSA	434	6,621	12	25	397	2,514	978	3,129	38%	15%	47%

APPENDIX 6C

APPLICATIONS FOR EXEMPTION FROM THE REQUIREMENT TO FLUORIDATE PUBLIC WATER SUPPLIES IN SA

According to a question asked in parliament in September 2002, 50 treatment works had been exempted because of optimum or higher levels of natural fluoride concentration in the water in that area.⁶⁷ The below table indicates the progress with applications, or exemptions, to fluoridate as at January 2003.

	No. of WSP's
Total exemptions applied for	114
Reasons	
- high natural levels	30
- upstream supplier may fluoridate	3
- small community	22
- Technical or economic reasons	22
- No reason supplied	37
Permanent exemptions granted - high natural levels	30
Total temporary exemptions granted	44

(Source: from Department of Health, Jan 2003. Numbers should be seen as indicative of trends only)

⁶⁷ National Assembly, 13 September 2002. Question Number 1371

CHAPTER SEVEN

SUMMARY AND CONCLUSIONS

J. Haarhoff, RAU Water Research Group

7.1 Introduction

Water fluoridation for South Africa has been intensely debated since the tabling of the first draft regulations almost ten years ago. It has now advanced to the point where water suppliers are bound by a promulgated set of regulations to register for fluoridation, and implement it where required. The purpose of this report is therefore not to reopen the debate and start from scratch. It is rather to collect a body of locally relevant information meant to assist all the role-players in their task to implement water fluoridation – those grappling with its technical aspects, and especially those that have to inform and advise the public and their political representatives.

The approach is therefore to consider a broad range of issues, trying to address all the issues that had been raised during the South African debate and, of course, the international debate, which had started fifty years earlier. The likely value of the different chapters are anticipated to be:

- The complex relationships between human health and fluoride are addressed first, as this is the area most emotionally and vehemently debated. The arguments around health had been mostly discounted during the political debates prior to the approval of the legislation, but the summary provided here would be useful for a public communication strategy.
- The impact of water fluoridation on the environment (which receives the return flows) is a new contribution, which sheds new light on an aspect not quantified before. The methodology described as well as the preliminary findings will be of valuable assistance to water suppliers in future as they have to address this issue in each individual case.
- An immediate concern is the procurement, handling, cost, dosing and measurement of fluoride at the water treatment plant. These technical issues are discussed in their own chapter, which will help the water suppliers to avoid and prevent the many smaller, but potentially disastrous technical problems inherent in any engineered system.
- The chapter on economic issues demonstrates when, and to what extent, water fluoridation is the most economical method to address the problem of dental caries. This framework of analysis as well as its general findings will assist the Department of Health in determining which water suppliers should be exempted from water fluoridation on the basis of size and cost.
- The final chapter addresses a wide range of social and legal issues. These are all arguments that have been raised in the national debate at some point or another. By logical grouping and coherent analysis, in the light of local legislation and the latest legal opinions, it will be a valuable reference to professionals dealing with water fluoridation at all levels.

7.2 Medical and Dental Issues

There is no debate about the fact that fluoride has beneficial dental effects at a low dosage, as well as harmful dental and other health effects at higher dosages. What is debated, however, is the *threshold* concentration at which the effects turn from beneficial to harmful, and the *nature* of the harmful effects. These questions probe a highly complex issue on which there is very little scientific certainty or even agreement. A simple (and usual) regurgitation of pros and cons would only fuel the “all benefit” and “all

harm” sides of a rather pointless activist debate unfortunately seen too often. The intention was to provide a balanced picture (and inevitably this will be questioned from both sides!) by introducing a number of specific perspectives:

- To consider both human health data (often the road taken by the pro-fluoridation lobby to show that there is no harm) as well as animal and *in vitro* data (often the road taken by the anti-fluoridation lobby to point to all the conceivable problems be encountered). Both approaches have severe limitations - human epidemiological studies are insensitive to small but real effects, whereas animal and *in vitro* studies have obvious problems in extrapolating their results directly to humans. They should not be used in opposition, but as complementary tools to probe a complex issue such as water fluoridation.
- To provide the logical, intuitive framework of *health risk assessment* to enable the reader to weigh and compare the data from different studies; an approach which has found general and popular application in the past decade.
- To draw attention to the South African reality of a non-homogenous population where there are huge gradients in income, nutrition levels and immuno-compromise. Some population groups are probably more sensitive to fluoride than others; an aspect requiring serious consideration by policy-makers.

The specific findings of this chapter are summarised as:

- The evidence for toxic effects is well established. For dental and skeletal fluorosis reasonable thresholds have been established, but the evidence is not available to be able to establish the threshold for other potential toxic effects.
- The evidence for carcinogenic effects is inconclusive, as very little good quality research is available even though numerous studies have been published on the subject. The United Kingdom’s Medical Research Council Working Group looking at the subject (MRC, 2002) also concluded that there is no firm evidence linking water fluoridation to cancer, but the group recommended an updated analysis of the data on fluoridation and cancer rates be carried out.
- The York Review (recognised as being one of the better reviews carried out on the subject of water fluoridation) indicated that water fluoridation results in an average improvement of 14.6% of caries-free children, with a median improvement of 2.25 caries free teeth (McDonagh *et al*, 2000). Some local studies (not performed at the required level of stringency to be included in the York Report) indicated better results where fluoride intake was increased.
- The WHO (2002) states that there is a narrow range between intake associated with harmful and beneficial effects.
- The total dietary intake of fluoride is more than just that from water. Moreover, there are other ingestion routes such as dust, air and toothpaste. Very little is known about true total exposure to fluoride, either here or in the rest of the world.
- A health risk assessment, assuming water fluoridated at the maximum level of 0.7 mg/l as the only entry route, indicated a hazard index of 0.4, which is lower than the theoretical threshold of 1.0. When estimates of the other entry routes are added to that of water, the hazard index jumps to 2.0. In this case, the non-water routes account for a hazard index of 1.5 on their own. It should be noted that these estimates are not absolute and associated with a wide range of uncertainty. It nevertheless supports the WHO view that the margin between harmful and beneficial effects is narrow. The Department of Health should therefore carefully set the water fluoridation levels.
- In developed countries there is little evidence that water fluoridation reduced social inequalities (McDonagh *et al*, 2000). It is not clear whether this finding can be extrapolated to developing

country conditions such as found in South Africa where many people do not have access to either toothbrush or fluoride toothpaste.

- South Africa has a very large potentially sensitive sub-population that may experience the detrimental effects of fluoride at the proposed water fluoridation concentration. There are many unknown factors with regards to the toxicity and carcinogenicity potential of fluoride and this may be exaggerated in the immuno-compromised.

The uncertainties raised in this chapter can be partly resolved by research into the following areas:

- High quality epidemiological studies need to be carried out to examine all the possible adverse health effects of fluoride and water fluoridation, taking into account accurate exposure assessments. This will be extremely costly and time-consuming and is intended as a general recommendation to all countries practising water fluoridation.
- An indication of total exposure to fluoride of South Africans is needed. This includes fluoride ingestion from food, food prepared with water containing fluoride, toothpaste and mouth rinses, soil / dust, and via inhalation.
- An assessment of the sensitivity to the toxic effects of fluoride of the immuno-compromised needs to be investigated, as this has serious implications on health policy and recommendations for HIV+ and Aids sufferers.

7.3 Environmental Issues

The environmental impact of water fluoridation is driven by return flows, i.e. through the wastewater from urban areas when it is returned to the natural environment. Common sense dictates that the effect will be most severe either when the fluoride concentration is significantly elevated through water fluoridation, or when return flows make up a relatively large fraction of the flow in the receiving streams. In this report initial estimates for eight areas are presented using a mass balance approach in conjunction with average annual flow rates and median fluoride concentrations. After allowing for fluoridation to the maximum mandated level of 0.7 mg/l and adjudicating the effects against threshold concentrations based on existing South African water quality guidelines (allowing for a margin of error), the preliminary findings are:

- Problematic fluoride concentrations were found in five of the eight catchments studied, namely the Vaal River between the Barrage and the confluence with the Orange River, the Upper Crocodile and Pienaars River systems, the Sand River downstream of Virginia and Welkom, the Modder River upstream of the Krugersdrif Dam to the confluence with the Riet River, and at several points in the Waterval River system. Four of these potential problem areas would result from fluoridation of the Rand Water supply. This points to the Rand Water supply area as being the most critical area requiring further investigation.
- The results of the preliminary analysis did not indicate undue problems in the Msunduzi, Berg and Buffalo Rivers.
- Other potential problem areas need to be identified and, where warranted, investigated.

It should be stressed that these findings were based on a simplified methodology in order to obtain a first-order estimate of potential problem areas. For a detailed investigation into a specific catchment area, the methodology can, and should be, refined to address the following:

- Much of this report is based on median analyses that did not take proper account of hydrological variation. It is essential to investigate the effect of hydrological variation. Unusually wet conditions over the last few years would also have distorted the results, leading to under-estimation of fluoride

concentrations. A less biased analysis based on a longer hydrological sequence is required to give a more balanced view of the likely impact.

- The impact at future time horizons needs to be considered when larger effluent discharges will make a bigger contribution to base flow. Increasing water demands will also affect the operation of river systems, further magnifying the impact of fluoridation.
- The methodology employed in the initial analyses does not take proper account of storage effects in major dams, which would tend to elevate the fluoride levels due to evaporative concentration. These important effects need to be assessed.
- The simplifying assumption is made that evaporative concentration of fluoride does not occur through use. This assumption is reasonable for domestic and many smaller industrial processes. However, evaporative concentration does occur when steam is raised or water is used in cooling cycles. This would tend to increase the estimated fluoride concentrations.
- The limited nature of the investigation precluded collection of all relevant data. The impact of effluent discharged to rivers by industries was also ignored. This omission leads to under-estimation of the impact on downstream river systems. The latest water abstraction data, dam water balances, irrigation use, effluent flow and hydrological data need to be collected and processed to support in-depth investigations.
- The preliminary analyses ignore the possible effect of fluoride on irrigation. This may be a long-term effect, but eventually costly remedial measures may have to be implemented to drain salts from the soils. It should be noted, however, that fertiliser application also contributes significantly to the fluoride load; the relative contribution of water fluoridation should therefore be quantified first.

The recommendations, following from the desk-top study presented, are:

- Detailed assessments are required in the following priority areas - Vaal Barrage and downstream Vaal River system, Crocodile River, Waterval River, Modder River and Sand River.
- Further research should be aimed at determining which other areas warrant more detailed investigation. This should include the Molopo and Cowie River systems and other areas identified after discussions with all water boards and major water suppliers. Where applicable, preliminary evaluations should be carried out at a level similar to that described in this report.
- Fluoridation targets need to be optimised for each priority area to minimise the risk to downstream users and the natural environment.
- System modelling is required to properly assess hydrological variation and to account for both present and projected future conditions.
- Water use within major supply areas should be examined and effluent fluoride data collected to determine the extent to which fluoridated water would be concentrated before discharge as effluent.
- Research into the long-term accumulation of fluoride in irrigated lands, the impact on the crops grown and irrigation return flow quality is required.
- The time frame for implementation of fluoridation in certain sensitive areas should be revised to allow more time for the essential preparatory research to be completed.

7.4 Technical Issues

There are numerous practical matters to be considered by water suppliers before water fluoridation can be implemented. This aspect, unlike the other issues dealt with in this report, is fortunately dealt with extensively in the promulgated regulations. The focus of this section was therefore to critically examine the technical specifications contained in the legislation and to simply focus on those aspects that are not adequately covered. The main findings are:

- The three fluoride compounds legislated for use in South Africa are commonly used throughout the world and thoroughly covered by standard specifications.
- The larger water suppliers, should they implement water fluoridation, will probably use fluorosilicic acid as the fluoride compound of choice.
- The South African fluorochemical industry is confident that it can already produce this compound at acceptable quality and in adequate volumes to meet the projected water fluoridation needs.
- Delivery of the product will probably be by a number of dedicated bulk road tankers.
- South African road traffic legislation is adequate to enforce the safe, responsible transport and delivery of fluoride compounds by road to site.
- The storage, dilution, pumping and metering of fluoride at the water fluoridation plant do not require any additional design, construction and operating skills above those already available at water treatment facilities.
- There are numerous safety and disaster prevention devices suggested which normally do not form part of regular chemical dosing equipment at water treatment facilities. These require special attention during the implementation phase.
- The allowable tolerances for fluoridation dosing accuracy are strict and continued compliance will require special care and diligence.
- The single most difficult aspect of fluoridation control seems to be the accurate measurement of fluoride in water, a conclusion also borne out by inter-laboratory comparisons as well as operating experience from others who have been practising fluoridation for many years.
- The chemical reactions between fluoride and other compounds are well studied and can be quantitatively anticipated for specific situations.
- A potential problem of fluoride precipitation exists when fluoride is added in a high pH regime, or when fluoride is added at low pH in the presence of aluminium (possible in low-alkalinity water such as in the southern Cape).
- No downstream corrosion or other adverse effects on consumers are anticipated.
- An elaborate procedure is detailed for routine administration, in terms of the frequency and hierarchy of reporting.
- No standard formats and electronic back-up requirements for the different reports are specified, which may make further reporting or analysis unnecessarily tedious.
- The incident management and reporting procedures are sparsely detailed and may require further amplification.
- In the legislation and guidelines, much emphasis is placed on having a detailed, formal, written programme which will be the blueprint for all employees at all levels for dealing with normal operation, maintenance and disaster management – without giving any guidance on what is required. The development of such a comprehensive plan by each water provider is a costly exercise. There is a need for a generic blueprint programme, which can be amplified and adapted, to the specific needs of each water provider.
- The general Class III operator qualifications required are high and, depending on how the regulation is interpreted, may be a limiting factor to prevent widespread implementation of water fluoridation in South Africa.
- There is a definite and urgent need for fluoridation-specific training and certification for operators, prior to the full-scale implementation of fluoridation in South Africa.
- The total cost of water fluoridation seems to converge at about 2 to 3 c/kl for treatment plants larger than about 10 Ml/day. For plants smaller than 10 Ml/day, there is a sharp increase in unit costs due to the larger proportional capital cost component.

Based on these findings, the following recommendations are made:

- Design and implement a comprehensive training and certification programme for operators, designers and managers of water fluoridation systems
- Revise and upgrade the Technical Manual to comprehensively reflect South African legislation, local concerns and reporting requirements.
- Establish a benchmarking and networking system amongst water providers to improve the measuring accuracy of fluoride to ensure compliance to the strict dosage control ranges called for; alternatively, consider less stringent dosage control ranges.
- Develop a uniform and preferably electronic reporting system for automated submission and rapid review of water fluoridation records.
- The Regulations and Technical Manual require the submission, by each water provider, of a comprehensive programme that deals with all aspects of water fluoridation at all levels. As there are no guidelines or minimum requirements for this programme, it is recommended that a generic water fluoridation programme is developed to the satisfaction of the Departments of Health and Water Affairs, which can then be used as a standard template by the different water providers to detail their own programmes in a cost-efficient, time-efficient and uniform way.
- Assemble the typical water quality profiles at those South African water providers to implement water fluoridation, and systematically model the chemical speciation upon fluoride addition with a program such as MINTEQ. This will demonstrate to what extent the concerns about aluminium and other complexes with fluoride are warranted.

7.5 Economic Issues

The fundamental premise driving the South African water fluoridation legislation is that it can avert dental caries. In the absence of water fluoridation, dental caries have to be addressed by filling or other dental care. In this chapter, an economic cost-benefit analysis is conducted to assess whether, and under which conditions, water fluoridation is the better economic option. A number of assumptions were made for this analysis:

- The cost of water fluoridation was based on South African costs estimates. This ranges from about 2.0 to 2.5 c/kl for treatment plants with a capacity of 10 Ml/d or more, with a fairly steep increase in costs below this capacity.
- The cost of an average filling was estimated to be R158.95, based on South African dental rate scales.
- Water fluoridation was estimated to avert one filling every five years, equivalent to a reduction rate in dental caries of 20%.
- For negative health effects, environmental impacts and defluoridation needs, zero costs were assumed. The basis for this assumption was not information that these costs are indeed zero, but insufficient generally accepted information on their scale.

The cost-benefit analysis was carried out for two population sizes, namely populations of 100 000 and 5 000 respectively:

- For the population of 100 000, the economic benefits outstripped the costs by a factor of 4.4 times, thus indicating that water fluoridation is the better option. The economic rate of return of water fluoridation, in more formal terms, is 29% which is significantly more than the required minimum of 10%.

- For small populations of less than 5 000 people and small plants (fluoridating less than 2000 kilolitres per day) the operational and capital costs per capita increase substantially. Under these circumstances the benefit-cost ratio drops to 0.73 (less than 1) and the internal rate of return to 5% (less than 10%). The conclusion is that water fluoridation is economically unfavourable for small populations of less than 5 000.

The following further avenues of research are suggested:

- The fluoridation project is efficient in large metropolitan areas in South Africa if the intended dosage is indeed safe (has no negative health impacts), but it is inefficient in very small rural communities. It is deduced that at some intermediate population size the project becomes efficient. A more comprehensive cost-benefit analysis should be undertaken to determine this threshold.
- There is little doubt that the main limitation of this study is the lack of information on the negative health costs at fluoridation concentrations between 0.5 and 1.0 mg/l. This lack of information creates too much uncertainty and will cause cost-benefit analyses to yield inconsistent results. There is much empirical international evidence for assuming that it is safe to fluoridate water between 0.5 and 1.0 mg/l. In this case there are no negative health costs to worry about. However, some uncertainty remains about the other fluoride ingestion routes as pointed out in other parts of this report, which will continue to cast a shadow on the economic analysis unless better resolved and quantified.

7.6 Social and Legal Issues

A broad range of social and legal issues connected to water fluoridation are considered and discussed. Some of the findings pertinent to the implementation of water fluoridation in South Africa are:

- The Fluoride Regulations were lawfully made, in full accordance with the way in which powers and functions have been allocated between the 3 spheres of government under the Constitution.
- While Municipal Water Service Authorities are responsible for ensuring that water supply systems function properly, whether operated by themselves or by a Water Provider, any decisions regarding national and minimum water quality standards are legally the function of the Ministers of Health and Water Affairs, and not of the individual municipal councils or Water Authority.
- The outcome of any constitutional challenges will therefore depend on the strength of expert evidence, and the persuasiveness of the argument put forward by opponents to fluoridation.
- Legal liability will depend on the nature of the claim. Claims for the improper implementation of the regulations will be against the relevant Water Service Authority, while claims against fluoridation itself will be against the Minister of Health.
- Defluoridation of water supplies where natural levels exceed the recommended level of 0.7 mg/l is not required by the regulations. The responsibility of water service providers regarding natural fluoride levels above the recommended level needs to be clarified.
- Although the regulations are aimed at reducing the incidence of dental caries, particularly in poorer communities, many rural communities will in all likelihood never benefit from water fluoridation, due to technical constraints both in the short and the long term. Alternative measures of improving access to dental services and basic dental care must be implemented for these groups.
- There are fears that the cost of introducing water fluoridation will delay efforts to connect poor communities to piped water. However, DWAF has clearly stated in a presentation to the National Portfolio Committee that the provision of Free Basic Water remains the priority.

As can be expected with any new initiative, a number of questions regarding practical implementation remain. The following recommendations for further study are therefore made:

- It is recommended that the issue of defluoridation be investigated further, especially with regard to any possible obligation on Water Service Providers to reduce excessive fluoride levels. This could have significant financial implications for the municipalities concerned.
- For those sections of the population who will not receive fluoridated water, it is recommended that the Department of Health investigate the possibility of using other forms of fluoride in conjunction with education campaigns, in order to improve oral health amongst *all* South Africans.
- There is a need for greater clarity on the hierarchy of conflicting protocols for considering applications, and the application process. How will capacity to implement fluoridation be measured?
- Greater clarity is required on the matter of public comment, and the process to be followed by municipalities when receiving these comments. How will these comments be taken into account?
- Further investigation is required into the minimum recommended scheme size for implementing water fluoridation, both economically and technically.
- In order to reduce opposition, it may be necessary to clarify the purpose of the frontrunner process – is it intended to generate lessons to support broader implementation of water fluoridation in the near future, or are they longer-term pilots to determine the health effects of water fluoridation?
- It is recommended that research in South Africa be conducted in order to determine the relationship between socio-economic class, diet and oral health, particularly between rural and urban communities.

7.7 Closure

If nothing else, this study demonstrates that the water fluoridation legislation has sparked, and indeed deserves, a multi-faceted debate covering a broad range of expert areas and viewpoints. Water fluoridation has both beneficial and harmful effects; both direct effects as well as unintended knock-on effects. In a country as diverse as South Africa, it is obvious that one size cannot fit all. The South African legislation consequently calls for each water provider to individually register for water fluoridation, reflecting the unique requirements and constraints of each. It further requires individual consideration of each application, leading to either exemption, postponement or the setting of a fluoridation target for that particular supplier, which will then be followed by close monitoring on local, provincial and national levels.

This report will help water suppliers to identify their own constraints and problems, if any. In some cases, a limiting factor may be environmental concerns; this report provides guidelines for initial assessment and recommendations for more detailed studies. In other cases, a perceived problem may be costs or manpower requirements; this report provides preliminary cost estimates and the additional operational complexity of water fluoridation. There may be uncertainty on the legal position following new municipal legislation; this is explained and some preliminary interpretations are provided. Decision-makers at local level may be confused by what appears to be conflicting health views; this report points to the relatively narrow band between beneficial and harmful effects, and in which areas inevitable uncertainties remain.

The contributors to this study trust that it will help to pave the way to a rational, responsible implementation of the water fluoridation legislation in South Africa.