

forum on
fluoridation

2002

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Chairman's Introduction

It is a pleasure to present this report of the Forum on Fluoridation to Mr Micheál Martin TD, Minister for Health and Children, who established the Forum. This is the first major review of water fluoridation since it was introduced in Ireland in 1964. The report is a comprehensive review, which aims to inform members of the public, legislators and health professionals about the benefits and risks of water fluoridation for human health. An overview is made of research undertaken in Ireland and elsewhere on water fluoridation together with recommendations on future research and more stringent monitoring procedures.

The report was prepared after fourteen plenary meetings and several meetings of subgroups of the Forum during the past fourteen months. Individual members of the Forum made oral presentations to these meetings as well as seven persons from outside Ireland and seven persons from within this country. Every effort was made to strike a balance between presentations, which represented the views of individuals or groups in favour and against water fluoridation. The Forum is very grateful to all those who made oral presentations.

In keeping with the ethos of a Forum, as much time as possible was allowed for discussions between presenters and Forum members. All presenters were informed that one of the main objectives of the Forum was to examine scientific evidence for and against water fluoridation. Therefore, any claims about the benefits or dangers of water fluoridation had to be substantiated by recognised scientific studies and not by anecdotal evidence or individual experiences. In this regard, presenters were requested to provide references in internationally recognised scientific journals to substantiate their claims. By establishing this procedure at the outset, the Forum accepted a fundamental scientific tenet that any single piece of scientific evidence by itself remains hypothetical unless it can be repeated or confirmed by other scientists. Therefore, any such evidence must be submitted to examination by other scientists, usually by publication in recognised scientific journals after the submission has been approved by independent referees.

There is a comprehensive list of scientific references for those readers who may wish to do further reading on the technical issues reviewed in this report.

Another objective of the Forum was to address issues of concern to the Irish public as regards water fluoridation. The Forum, therefore, embarked from the outset on an extensive programme of public consultation to engage members of the public in its proceedings. In addition, Irish organisations and individuals who have expressed anti-fluoridation views in the media were invited to make oral presentations. Invitations to submit views to the Forum were advertised in the newspapers and on local and national radio stations. A website (www.fluoridationforum.ie) was established, which contained minutes of all plenary meetings as well as summaries of oral submissions to the Forum. The website will also contain the entire Report of the Forum.

Chairman's Introduction

The response from members of the public was excellent and the Forum wishes to express its grateful appreciation to all those who accepted the invitation to make submissions. Every effort has been made in this Report to address as many of the issues as possible raised in these and other submissions.

It was an honour and a most interesting experience to act as Chairman of all fourteen plenary sessions of the Forum and of one of its subgroups. I greatly appreciate the enormous commitment of their time and the conscientious manner in which the members approached this complex issue. As the list of members shows, the Forum was indeed, fortunate in having a distinguished membership with considerable relevant expertise in areas such as oral health, public health, chemistry, engineering, environment, food safety, law, social science and consumer affairs.

The completion of such a relatively large task within the time allocated is usually heavily dependent on administrative support. The Forum was very fortunate in having Ms Nessa O'Doherty as Secretary and Dr Miriam Owens as Rapporteur. The Forum gratefully acknowledges their excellent professional contributions throughout its activities and during the completion of this report. Thanks also are due to those who provided editorial assistance during the completion of this report.

The majority of the Forum's plenary sessions were held in the excellent facilities of the Dublin Dental Hospital and the Forum gratefully thanks Professor John Clarkson and his colleagues for the use of these facilities.

Patrick F Fottrell

Chairman

March 2002

Membership of the Forum on Fluoridation September 2000 to October 2001

Membership of the Forum

Professor Patrick F Fottrell, MSc, PhD, DSc, MRIA. Forum Chairperson. Former President and Professor of Biochemistry of National University of Ireland, Galway

Dr Wayne Anderson, BSc (Hons), PhD, MIFST, – Chief Specialist in Food Science, Food Safety Authority of Ireland

Professor William Binchy, Regius Professor of Law, Trinity College Dublin

Professor John Clarkson, BDS, MA, PhD, Professor of Dental Public Health and Dean of Dublin Dental School and Hospital

Dr Dominique Crowley, Deputy Chief Medical Officer, Department of Health & Children until 15/09/00, then – Lecturer, Department of Community Medicine and Epidemiology, University College Dublin until June 2001

Dr Elizabeth Cullen, MB, MSc (Community Health), Diploma in Pollution Control (Open), Co-Chair, Irish Doctors' Environmental Association, Thomastown, Kildare, Co. Kildare since December 2000

Dr Patrick Flanagan, PhD, BSc, Environmental Protection Agency

Mr Oliver Fogarty, BE, CEng, MIEI, MCIWEM, Engineering Inspector, Department of the Environment and Local Government

Ms Dorothy Gallagher, Vice-Chair, Consumers' Association of Ireland

Dr Gerard Gavin, Chief Dental Officer, Department of Health and Children

Ms Dora Hennessy, Principal Officer, Department of Health and Children (until April 2001)

Dr Howard Johnson, MRCPI, FFPHMI, Specialist in Public Health Medicine, Eastern Regional Health Authority

Professor Cecily Kelleher, Professor of Health Promotion, National University of Ireland, Galway

Mr Kevin Moyles, BSc, Regional Public Analyst, Dublin

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Dr Carmel Parnell, BDS, MPH, Acting Senior Clinical Dental Surgeon, North Eastern Health Board, and Irish Dental Association

Professor Miriam Wiley, MSc (Econ), PhD, Head, Health Policy Research Centre, The Economic and Social Research Institute, Dublin

Dr Miriam Owens, MB, MPH, MFPHMI, Rapporteur to the Forum

Ms Nessa O'Doherty, Secretary to the Forum, Department of Health and Children until November 2001

Dr Margaret Shannon, Forum Secretariat, Department of Health and Children

Mr Shane Devine, Secretary to the Forum, Department of Health and Children, from November 2001

The following were invited by the Minister as members of the Forum, but declined the invitation: Ms Darina Allen, and Mr Dick Warner and a representative from Voice of Irish Concern for the Environment (VOICE). The Minister also informed the Forum that he would be pleased to invite additional members if requested by the Forum. In this regard the Chairman suggested Dr Elizabeth Cullen, who accepted the invitation by the Minister to join the Forum.

Conclusions and Recommendations

Introduction

At its final plenary meeting on 25 October 2001, the members of the Forum discussed the conclusions to be drawn from the information and data gathered and assessed over the previous fourteen months. With the terms of reference kept to the fore, members were requested by the Chairman to give their views on the future of water fluoridation in Ireland. Specifically, their responses were sought to three questions:

- *Has water fluoridation improved the oral health of the Irish population?*
- *Is there scientific evidence that water fluoridation at a level of 1 part per million (mg /l) endangers human health?*
- *What recommendations would you make?*

The members present duly expressed their views on these three questions. Some of those who were unable to attend the meeting subsequently submitted their views, and the recommendations and conclusions presented below are based on the views of the majority of members of the Forum. In addition, a number of members gave the opinions of the particular organisation or professional body they represented rather than their own view.

Overall Conclusions

- *Water fluoridation has been very effective in improving the oral health of the Irish population, especially of children, but also of adults and the elderly.*
- *The best available and most reliable scientific evidence indicates, that at the maximum permitted level of fluoride in drinking water at 1 part per million, human health is not adversely affected.*
- *Dental fluorosis (a form of discolouration of the tooth enamel) is a well recognised condition and an indicator of overall fluoride absorption, whether from natural sources, fluoridated water or the inappropriate use of fluoride toothpaste at a young age. There is evidence that the prevalence of dental fluorosis is increasing in Ireland.*

Recommendations

The recommendations of the Forum on water fluoridation are intended to assist health care providers, public health officials, policy makers and the public in achieving maximum protection against dental decay and to minimise the occurrence of dental fluorosis.

In making its recommendations the Forum has been cognisant of two recent strategy documents: *Quality and Fairness: A Health System for You* (Health Strategy 2001) and *Making Knowledge Work for Health* (Health Research Strategy 2001).

- *Quality and Fairness: A Health System for You* outlines a number of measures that will underpin an evidence-based approach to the planning, monitoring and delivery of health care on a national level.
- *Making Knowledge Work for Health* outlines a research and development function for the health boards/Authority based on a partnership approach with an international dimension.

It is envisaged that the forthcoming National Health Information Strategy will support processes and procedures to ensure easier access and best use of available health information, including the exploitation of modern information and communications technology.

The precise manner in which some of the Forum's recommendations will be implemented may depend on the structures and processes arising from these Strategy documents.

For example, one of the functions of the proposed Health Information and Quality Authority is to oversee health technology assessment. As water fluoridation is a well-established health technology, future assessments of it may be the remit of this authority.

The Health Boards Executive (HeBE) provides an important means of enabling the health boards/Authority to operate jointly on matters where a national approach to implementing a programme or service is required. It is envisaged that the HeBE will play a major role in ensuring the consistent delivery of a national water fluoridation programme of the highest standard.

The recommendations are presented under a number of headings, which reflect the main issues covered in the Forum's report. Reference to the items from the above strategy documents will be made as appropriate.

Recommendation 1

Policy Aspects of Water Fluoridation

- *The fluoridation of piped public water supplies should continue as a public health measure, subject to the other recommendations contained in this report.*
- *In the light of the best available scientific evidence, the Fluoridation of Water Supplies Regulations, 1965 should be amended to redefine the optimal level of fluoride in drinking water from the present level (0.8 to 1.0 ppm) to between 0.6 and 0.8 ppm, with a target value of 0.7 ppm.*
- *The amended Regulations should reflect advances in the technology of fluoride monitoring and testing and also the most recent international specifications for the quality of the products used in the fluoridation process.*
- *An Expert Body should be established to implement the recommendations of the Forum and to advise the Minister for Health and Children on an ongoing basis on all aspects of fluoride and its delivery methods as an established health technology.*

Against a background of exposure to multiple sources of fluoride and changes in the rates of dental decay and dental fluorosis on both a population and individual level, it is considered appropriate to redefine the optimal level of fluoride in the Irish drinking water, taking account of these altered circumstances.

In the light of both international and Irish research which shows that there is an increasing occurrence of dental fluorosis, the Forum recommends the lowering of the fluoride level in drinking water to a range of 0.6 to 0.8 ppm, with a target of 0.7 ppm.

In the opinion of the Forum this level of fluoride would be sufficient, along with the continued use of fluoride toothpaste, to maintain meaningful reductions in dental decay rates while reducing the occurrence of dental fluorosis.

The validity of this recommendation should be further assessed when the results of the National Survey of Children's Dental Health and the Food Safety Authority of Ireland's study of infant feeding are available.

The Expert Body should have multidisciplinary representation, including dentistry, public health medicine, toxicology, engineering, management, environment and the public, and should draw upon national and international expertise, including that of the oral health care industry. It is envisaged that this Expert Body may be subsumed into the Health Information and Quality Authority proposed in *Quality and Fairness: A Health System for You*.

Recommendation 2

Technical Aspects of Water Fluoridation

- *Guidelines/codes of practice and audit processes should be developed to support ongoing quality assurance of all aspects of the water fluoridation process and should take account of results of both Irish and international research.*
- *External audit procedures of existing fluoridation plants should be put in place to monitor the performance of existing plants and should be part of the specification of new plants. Audit results should be included in annual reports on water fluoridation produced by relevant fluoride monitoring committees.*
- *The standards and quality of each fluoridation plant should be assessed and decisions made as to the appropriateness of the continued use of inefficient plants.*
- *Fluoride monitoring and analytical and reporting procedures should be updated to reflect modern technologies and to facilitate timely reporting of all drinking water fluoride levels. These results should be made available in an appropriate format so that compliance with regulations can be monitored. The results should be freely available for public scrutiny.*
- *Raw water should be checked for fluoride levels before fluoridation takes place, in compliance with the current Regulations.*
- *The Eastern Regional Health Authority, currently responsible for purchasing the fluoridating products on behalf of the country's health boards, should ensure compliance with the amended Regulations specifying the quality standards of the products used in the fluoridation process.*

The Expert Body or its equivalent function in the Health Information and Quality Authority, in collaboration with the Health Boards Executive (HeBE), may have a key role in the implementation of the above recommendations.

Recommendation 3

Fluoride Toothpaste

- *The Forum recommends the continued use of fluoride toothpaste in fluoridated and non-fluoridated areas because of the additive benefit from the combination of fluoridated water and fluoride toothpaste.*
- *Parents should be advised not to use toothpaste when brushing their children's teeth until the age of 2 years. Prior to this age parents can brush their children's teeth with a toothbrush and tap water. Professional advice on the use of fluoride toothpaste should be sought where a child below 2 years of age is considered to be at high risk of developing dental decay.*
- *Parents should supervise children aged 2 to 7 years when brushing their teeth and should ensure that only a small, pea-sized amount of fluoride toothpaste is used and that swallowing of the paste is avoided (see photograph).*
- *Paediatric toothpastes with low concentrations of fluoride require further research before the Forum can recommend their use.*
- *Guidelines for the use of oral health care products in childhood should be developed for use by all involved in advising members of the public on health care matters. The Expert Body will play a key role in the development of these guidelines.*



Recommendation 4

Oral Health Care Industry

The Forum acknowledges the contribution of the oral health care industry in improving the oral health of the population. The Forum suggests that the industry should take a number of steps to reduce the risk of inappropriate use of fluoridated products by consumers, including the following:

- *Labelling of fluoride products in a manner which is better understood by the general population and especially by those with low levels of literacy or visual impairment*
- *The use of clear and understandable instructions on all fluoride product labels, in particular symbols/pictures to describe the appropriate amount of toothpaste to be used by children*
- *The provision of child resistant containers for mouth rinses and fluoride supplements to prevent inappropriate ingestion of these products by children.*

Recommendation 5

Infant Formula

- *Infant formula should continue to be reconstituted with boiled tap water in accordance with manufacturers' instructions. Alternatively, ready-to-feed formula can be used.*
- *The use of bottled water to reconstitute infant formula is not recommended unless the labelling indicates its suitability for such use.*

These recommendations take account of Recommendation 3 regarding the appropriate use of fluoride toothpaste for young children and Recommendation 1 regarding the reduction in the level of fluoride in drinking water.

Recommendation 6

Fluoride Research

- *All future research undertaken should be consistent with the research philosophy as outlined in the Health Research Strategy.*
- *The Expert Body should prioritise designated research in areas relevant to fluoride, and appropriate funding should be made available.*

- *Ongoing research related to fluoride should continue to be evaluated by the proposed Expert Body and expanded to deal with new emerging issues.*
- *Research related to fluoride should include the collection of relevant data on general health.*
- *In view of the acknowledged importance on a worldwide basis of research in the area of fluoride and oral health, the health board research programmes currently in place should continue and be further developed to augment the world body of information on fluoride for the benefit of all.*
- *The current 10-year cycle of adult and child dental health surveys should continue. In addition a rolling programme of oral health surveys every second year for a selected age group of children should be implemented.*

In addition to research on fluoride, eating practices and other oral health related behaviours, the new programme of research should include any areas of research related to general health considered appropriate by the proposed Expert Body. This research should complement that already available from other well-established population health surveillance systems.

Recommendation 7

Education, Information and Public Participation

The Forum's report is a comprehensive review of water fluoridation aimed at informing the public, legislators and health professionals about the benefits and risks of water fluoridation for human health.

As a response to calls for greater democratic, transparent and participatory policy processes, and in line with *Quality and Fairness: A Health System for You* which highlights the need to support improvements in the availability and quality of health information, it is essential to provide the general public and special interest groups with factual information on all aspects of water fluoridation including a full account of the work of the Forum.

This will require the development of a communication strategy to ensure that an informed debate takes place at all levels, i.e. the political arena, the media and on a community basis.

A multi-tiered approach will provide accessible and appropriate information for the public as a whole and for specific special interest groups. A number of approaches are set out below:

- *Media analysis and discussion in both the national and regional press to ensure widespread dissemination of the findings of the Forum.*

- *Further information from the report itself and from the Forum's website.*
- *National and local radio and television coverage to add to this information flow.*
- *Short video presentation of the main issues, accompanied by explanatory leaflets, made available to schools and local libraries, for example.*
- *Regional public meetings with a panel of multidisciplinary experts available to present information and to respond to questions and concerns expressed by the general public or by any special interest group. Such meetings could be convened at the request of local interest groups, for example local authorities, community groups or consumer organisations.*
- *Following completion of this exercise it is recommended that surveys or other methods be undertaken to measure the public response to the findings and recommendations of the Forum to help inform policy makers and legislators about public attitudes to water fluoridation.*

The aim of these initiatives will be firstly to increase public awareness of water fluoridation and its context and secondly to elicit public attitudes and values. The Expert Body in consultation with the Dental Health Foundation Ireland, and other appropriate bodies will determine the means whereby these public participation initiatives will be organised.

Recommendation 8

Public Health and Professional Practice

- *Oral health as an integral part of general health should be included in the overall provision of health care and in the design of health promotion programmes and initiatives.*

Issues which have arisen in the debate on fluoride may have caused some public and professional concern with regard to the benefits and risks of water fluoridation. From a public health point of view all involved in the public health profession should become familiar with the findings of this Forum and be able to give balanced and scientific information to the public.

As adults and the elderly benefit from water fluoridation, the role of fluoride in preventing dental decay in this population group needs to be promoted. Health care professionals should therefore deliver advice on oral health along with advice on general health care matters. The maintenance of good oral health will have a major impact on the overall quality of life of the elderly.

Additional Views and Conclusions

The Consumers' Association of Ireland (CAI) took a neutral stance on the question of the benefits and risks of water fluoridation. The CAI council had voted that consumers should have choice in this issue and that as mandatory water fluoridation does not offer choice, the CAI opposes the continuation of water fluoridation. It is the recommendation of the Consumers' Association of Ireland that the Government should now cease adding fluoridating chemicals to the piped drinking water.

The Irish Doctors' Environmental Association (IDEA) likewise adopted a neutral stance on the benefits of water fluoridation, and expressed its opposition to the continuation of the fluoridation of drinking water supplies. The association has concerns regarding the addition of fluoride to the water supply, on the grounds of unknown dosage, particularly with regard to infants. It also has concerns regarding contaminants and the possible interaction of fluoride with other drugs. The association believes that the ingestion of fluoride should be a matter of choice, and that dental decay is best prevented by dietary measures and improved dental hygiene.

Acknowledgements

In its 14 months of activity, the Forum has been assisted very greatly by a host of organisations (governmental and non-governmental), professional bodies, individual experts and specialists, and the general public. It is indebted to so many that it is impractical to list individually all those who contributed in a wide variety of ways to the work of the Forum. It is therefore the hope of the Forum that everyone who helped it will accept this sincere acknowledgement of his or her invaluable contribution. Without the wide range of comment, opinion and criticism expressed by members of the public, on the one hand, and the diverse body of dental, medical and scientific views of experts in their respective fields, on the other hand, the work of the Forum would have been much more difficult and its outcome incomplete.

The Forum would also like to acknowledge its debt to three persons, in particular – Ms Nessa O'Doherty, Secretary to the Forum until November 2001, Dr Miriam Owens, the Forum Rapporteur and Mr Shane Devine, Secretary to the Forum since November 2001. In their respective areas, they have made an immense contribution to the Forum, which is greatly appreciative of their efforts. Finally, the Forum must express its gratitude to Professor John Clarkson, Dean, and the Board of the Dublin Dental School and Hospital for their very generous provision of a venue and facilities for the majority of meetings.

Methodology of the Forum

Despite the conciseness of its terms of reference, the Forum was aware from the outset of the enormity of the task involved, and at its first meeting key decisions were taken as to how it should best operate. The only serious disruption of its programme was caused by the travel restrictions imposed following the outbreak of foot-and-mouth disease, which resulted in the cancellation of the March 2001 meeting and the putting back of the schedule by one month. A total of 14 plenary meetings and a number of Sub-Group meetings were held. It was agreed by the Minister for Health and Children that the deadline for submission of the Forum Report would be deferred to the end of October.

The Forum also decided at the outset that it would seek an input from national and international experts on fluoridation, holding views opposed to and in favour of the fluoridation of drinking water. Thus, from the second meeting onwards a significant proportion of the proceedings was devoted to the delivery of presentations to members by the invited experts. The speakers were requested to provide a written version of their respective presentations, so that their contributions – which assisted the Forum immeasurably – would be on the Forum record and in due course available to the public. In this regard, it may be mentioned here that all these contributions will be available in summary format on the Forum website.

The information-gathering phase of the Forum's activities continued until mid-2001, but during this period there were important parallel activities. As the Report of the Forum would constitute the only formal presentation of its findings and conclusions, it was considered essential that from a very early stage all practical steps should be taken to facilitate what would be a very great editorial exercise. Accordingly, a rapporteur was appointed to assist the Forum in this and other respects, and throughout 2001 the rapporteur was active, first, in many technical tasks of framing the Report in consultation with members and, then, in gathering, collating and editing the many contributions on the respective topics which would be covered in the Report.

Concurrently, the Forum set up Sub-Groups, to deal with such matters as consultation with the public, toxicological implications of fluoridation, ethical aspects, dental and general health considerations, and – later on – editorial matters. The membership of these groups varied in size, but all comprised members of the Forum with particular expertise in the respective subjects at hand. Whenever a Sub-Group felt it needed additional expert input, its members met with outside experts. This approach had the advantage that the respective expert groups could operate between meetings, without distraction by matters outside their remit. The output from these groups formed a key element in the preparation of the Report.

Throughout its activities the Forum was supported greatly by the Secretariat, whose input was critical. Although there were many functions to be carried out, not least in the preparation and distribution of a large volume of documentation, perhaps the most demanding task was acting as a contact point with the public during the extremely important consultation exercise

Presentations and Submissions

Submissions to the Forum have been summarised and are displayed on the Forum's website www.fluoridationforum.ie The following procedures were agreed by the Forum for delivery of presentations. Members of the Forum were invited by the Chairman to make suggestions for presentations on all aspects of water fluoridation within the terms of reference of the Forum, while keeping in mind the importance of having a balance between those in favour and those opposed to water fluoridation.

The Forum requested each presenter to submit a summary of his/her presentation beforehand if possible or as soon as possible afterwards. All claims and conclusions about water fluoridation and its alleged benefits or ill-effects should be substantiated by evidence of publication in peer-reviewed journals or by the recommendations from recognised international health authorities such as the World Health Organisation and the Centre for Disease Control and Prevention in the United States.

Members of the Forum were requested by the Chairman to submit questions or issues beforehand, which they wished to have addressed by presenters. It was also agreed that in keeping with the rationale of a Forum, as much time as possible should be given for discussion of presentations. Members agreed that every effort must be made to engage and encourage members of Irish organisations such as VOICE (Voice of Irish Concern for the Environment), the many consumer interest groups and environmental organisations to make presentations on their views on water fluoridation. Members of the general public would be encouraged through advertisements in the media to make submissions.

One presenter requested a response to his submission and the response of the Forum to this request will be presented on the Forum website. The final Forum Report has taken account of the issues raised in this submission.

A Note on Units and Terms

In order to avoid confusion for the reader by the alternative units in which fluoride concentrations may be expressed, the Forum has decided to use the term *parts per million* (expressed in terms of the chemical substance F) consistently throughout this Report. Where unavoidable (as occasionally in an Appendix), other units may be quoted in parallel.

One part per million of fluoride (F) is equivalent to

One milligram fluoride (F) per litre of water (1 mg/l)

and also to

One thousand micrograms fluoride (F) per litre of water (1000 µg/l F).

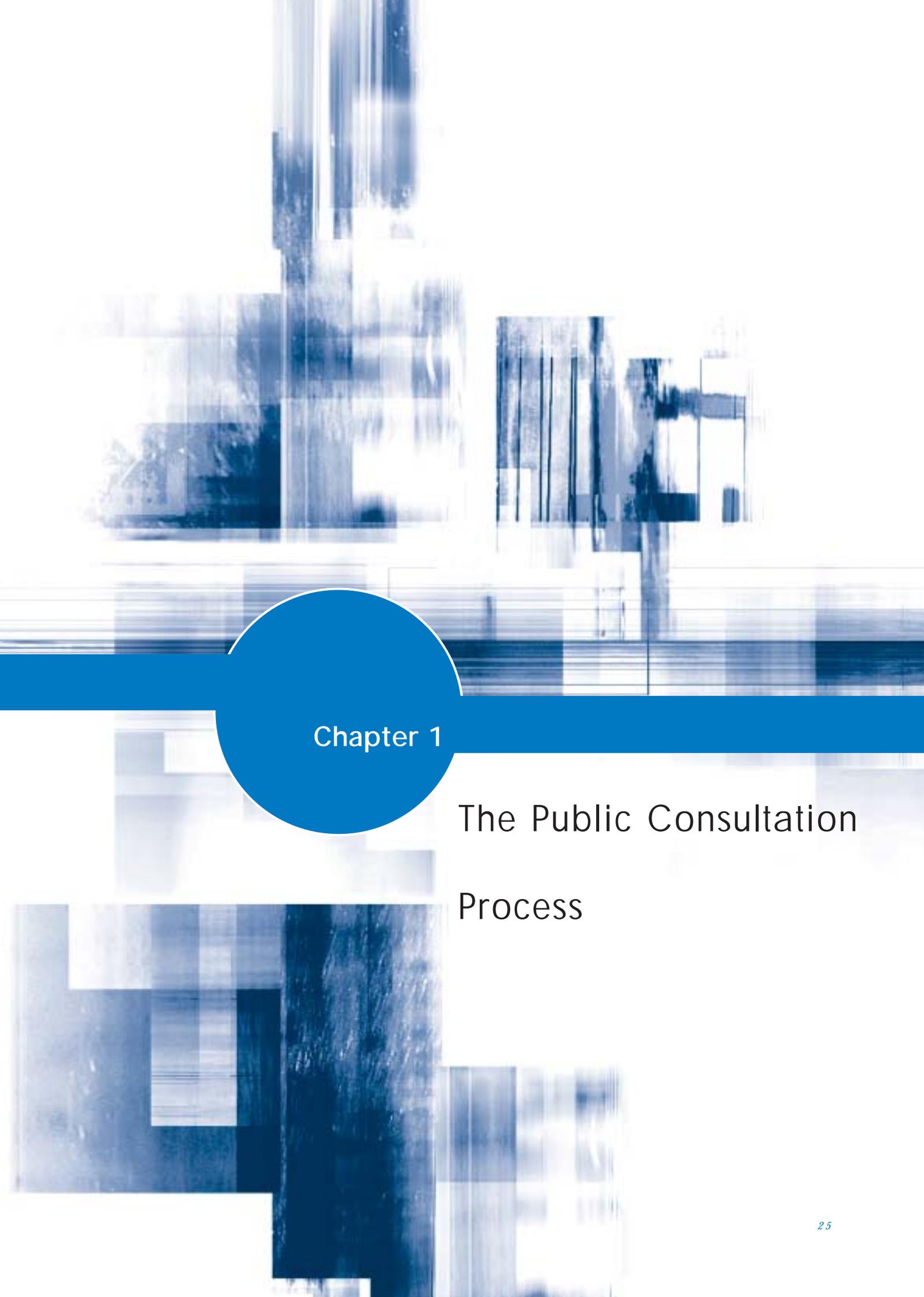
It should be noted that in technical documents and sources the latter units are customarily used to express concentrations, but the term 'parts per million' is nonetheless very widely used.

The fluoridation additive, H_2SiF_6 , has the alternative chemical designations hydrofluosilicic acid and hydrofluorosilicic acid. It is also referred to on occasion as hexafluorosilicic acid. The Forum has decided for the sake of consistency to use the term **hydrofluorosilicic acid** throughout the Report. However, its use is supplemented at times by that of the common abbreviation **HFSA**.

The Food Safety Authority of Ireland

The Food Safety Authority of Ireland (FSAI) report on infant feeding and fluoridated drinking tap water is presented in full in Appendix 18. To reflect its status as a complete report in itself it is presented here with its own table of contents and bibliography.

A summary of this report is available as an insert in the Forum's Executive Summary.

The background features a blurred, high-angle photograph of a modern building with a glass facade. A prominent blue circular graphic element is positioned in the lower-left quadrant, partially overlapping a horizontal blue bar that spans the width of the page.

Chapter 1

The Public Consultation Process

The Public Consultation Process

Introduction

The levels of public interest in and of concerns about the consequences of the fluoridation of public water supplies were among the factors which influenced the Minister for Health and Children in his decisions to establish the Forum on Fluoridation and to require that its deliberations should be completed within the relatively short period of one year from its commencement date. In introducing the Forum the Minister stressed that public consultation would be a key element in this investigation of fluoridation in all its aspects.

The importance of ascertaining the views of the public has been recognised from the commencement of the activities of the Forum, and the Chairman has articulated the members' views concisely:

A Forum, by definition, deals with issues of public concern. The Forum on Fluoridation values the opinion of the public and encourages discussion - to this end it has invited all Irish individuals and organisations as well as overseas experts to express their views on water fluoridation. We have had many submissions and presentations in response to our invitations ...

The submissions from non-governmental, professional and public bodies, and national and overseas experts in many fields (not just fluoridation) contain much information and comment, often of a highly detailed medical or scientific nature, and they have made an invaluable contribution to the considerations which are elaborated on in the main body of this Report. These submissions have been given due consideration throughout this Report.

Risk and Hazard

As society developed over time, the major hazards to humans were those posed by nature. In the modern world the acts of individuals or corporate bodies may also involve serious hazards to other members of society. Minimising the exposure of citizens to hazards created by nature or by human acts is an important function of governments.¹ When considering whether to impose safety measures, the government has to balance the benefits that will be achieved from reducing or eliminating exposure to a hazard against the possible harmful effects that the measure will involve. This process involves what is sometimes described as 'risk evaluation'.

A risk is not the same as a hazard. A hazard is an intrinsic propensity to cause harm. Natural phenomena, physical substances or human activities will be hazardous if they have an intrinsic propensity to cause harm. A risk is the likelihood that a hazard will result in harm.

A risk can be evaluated once the nature of the hazard and the degree of exposure to it are identified. Risk evaluation involves considering both the likelihood that a hazard will cause harm and the severity of the harm that is threatened.¹

In order to ascertain the concerns of the public with regard to water fluoridation and to determine how risks were perceived a public consultation process was undertaken.

Views of Members of the General Public

As the questions being addressed by the Forum were not the preserve of specialists or of bodies or groups with specific interests but were matters of great concern to the whole population, the Forum made every effort to ascertain the views of the consumers of public water supplies.

The approach adopted by the Forum was to place prominent advertisements in the national press inviting submissions from all interested parties, as the Chairman has pointed out. There was no restriction – other than an essential, though acceptable, time deadline – on the manner in which views might be expressed by respondents to the press invitation.

To facilitate such views a form was available on which members of the public could give their opinions on some specific points and also express their views on any matter related to fluoridation, continuing on supplementary pages if desired. The methodology of the questionnaire survey is explained in Appendix 1, which points out that the comment forms were available to all on request from the Forum Secretariat and were returnable post-free. The availability of the comment form was brought to the attention of the public in press notices and in a series of radio advertisements, which had a wide listenership. In all, over 900 completed forms were returned to the Secretariat, which also received over 100 letters and e-mails, bringing the total number of responses to almost 1,050. The comment form is presented in Appendix 2.

Some Criticism of the Forum

The design of the comment form was both criticised and lauded by respondents but it proved its worth by being successfully used by some 900 respondents who expressed a wealth of answers, views and opinions to the Forum. The view was also expressed that the form should have been sent as a matter of course to every household in the country, a suggestion of considerable merit. Much as the Forum would have wished to extend its consultation with the public, by such action for example, it was constrained by the limited overall time available for completion of its deliberations.

The criticism referred to is perfectly valid and reasonable, and while it relates to a specific Forum activity, it is among a great number of adverse comments (discussed later) expressed at times with considerable feeling by respondents to the consultation.

The hallmark of the responses has been the candour and conviction of the views expressed by the respondents. Irrespective of their viewpoint, the individual submissions have beyond all doubt represented the views of many members of the public. Clearly, the respondents seized the opportunity to express their opinions with enthusiasm and vigour, and the Forum is indebted to all of them for their views and criticisms.

While there were many critical comments made in the responses, they – almost without exception – reflected a constructive approach by the respondents. As such, though their content might not always be palatable to someone with a different viewpoint, they have been welcomed greatly by the Forum as a vigorous and genuine contribution to an important debate.

Unfortunately, the Forum has also had to face criticism of a rather less tenable nature. Indeed, some of it demands rebuttal at this early point in the Report. Reducing the debate on fluoridation to the absolute (though not actually valid) minimum results in the simple alternatives ‘pro’ or ‘anti’. It is a quite understandable assumption by some that all concerned with the administration and application of the fluoridation procedure are ‘pro’ – for example the health authorities, dental experts and so on. Also it is reasonable to conclude that members of some environmental and consumer interest bodies are ‘anti’, on the basis of their public statements.

The Forum was established by the Minister for Health and Children as an independent body made up of a college of persons with diverse views, responsibilities and experience, who have addressed the brief of the Forum with total commitment. Accordingly, ‘pro’ and ‘anti’ considerations did not arise during the investigatory work of the Forum, and it was only in the framing of the Recommendations that Forum Members expressed their views in this respect.

Clarification of Some Misconceptions

It is not coincidental that the topic of public consultation should be dealt with at the beginning of this Report. There are various reasons for this.

First, in line with the definition of a Forum already quoted, ‘public concern’ is of paramount importance. Accordingly, the contents of the Report – the result of the Forum’s activities – must reflect that concern as revealed by the public consultation.

Second, it is important that the public be reassured that their views do matter and are being taken into account by the Forum.

Third, while the majority of the concerns of the public will be addressed in later sections, it is appropriate here to discuss a small number of points about which there are misconceptions.

Unless this is done at the start, serious misinterpretations of the Report may result later on.

The Origin of The Fluoride Additive

The fluoridation agent currently used in Ireland for addition to drinking water supplies is hydrofluorosilicic acid (HFSA; H_2SiF_6). It has been claimed repeatedly, and is consequently widely believed, that this is 'a waste product from the phosphate fertiliser industry, mainly in the Netherlands'. This is **not** the case. The HFSA used in water fluoridation is a **primary product of production**; that is, it is the product of a specific manufacturing process, as explained later in this Report (Appendices 11 & 12).

It is also worth pointing out that, contrary to many statements, the term 'by-product' is not to be confused with 'waste'. HFSA has been described in the media as a 'by product of the fertiliser industry'. A by-product is the term applied to a substance which is also produced (in lesser amounts) in a process primarily intended to produce something else. If a by-product has no intrinsic or commercial value it may well be disposed of or regarded as 'waste'. It may also be noted, similarly, that while 'waste' may be something obnoxious or hazardous it may equally well be something inoffensive but without value. An example of a useful by-product is molasses, which arises in the production of sugar.

The corrosive nature of hydrofluorosilicic acid has also been widely reported and has aroused fears among some consumers. The raw undiluted chemical hydrofluorosilicic acid *is* very corrosive and is a strong acid, necessitating great care and suitable safety precautions among those handling it. However, when it is added to water in the correct amount and diluted (1 litre of acid added to approximately 110,000 litres of water) the resulting solution of HFSA – the drinking water – is devoid of any corrosive properties. The consumer is frequently, and irresponsibly, misled by implications that the unquestionably harmful properties of the raw additive are carried through to the diluted version, which is drinking water. Chlorine is a toxic gas in its natural state, yet is inoffensive and undetectable to the senses in properly prepared chlorinated drinking water. The concentrated form of acetic acid is a very pungent, unpleasant liquid, but a solution in water of about four per cent strength is to be found in vinegar.

The Composition of The Fluoride Additive

Many of the responses to the survey expressed fears about the presence in the hydrofluorosilicic acid additive of such substances as antimony, arsenic, cadmium, copper, lead and uranium, among others. There are European Union limits for all of these substances, which must be controlled in water for human consumption. The various limits permitted reflect the different toxicities of the aforementioned substances to humans. Cadmium and lead, for example, are very toxic and are subject to strict limits.

The Forum would agree completely with the widely expressed view that the use of chemical additives to drinking water should be minimised, but it must explain that many of them are, in fact, unavoidable in the present day, largely because of environmental pressures on raw water sources resulting from both urban and rural development. It is also important that the use and occurrence of additives be seen in true perspective, and that concerns are reserved

for those substances the presence of which does pose an actual or potential hazard. The question of fluoride dosage, both by the addition of HFSA at the water works and by the ingestion of fluoridated drinking water in the home is addressed in depth in Chapters 9 and 10.

Returning to the hydrofluorosilicic acid additive and its minor constituents or contaminants, the results of detailed analyses of the additive carried out by Enterprise Ireland are presented in Appendices 12 & 13 and they show the presence of a variety of minor constituents, including arsenic, cadmium, lead and selenium, for example. In order to put the significance of these data in perspective, the following points should be noted. The detection of a given substance in a material under analysis may not have any significance for human health. Major developments in analytical methodology and instrumentation, which have occurred in recent years, have important benefits and consequences. A decade ago, the approach to the analysis of drinking water using the best available technology involved the drawing up of a list of substances to be measured followed by the analysis for each substance in turn. The corollary of this was that there were no 'extra' data; analysis was for the nominated substances and was sufficiently demanding on resources to preclude the carrying out of unrequired or unrequested measurements. With the latest available techniques, however, it has become possible to carry out ultra-sensitive analysis for many substances in a single analytical run, so that instead of there being figures for, say, six metals (from six separate analyses) in a drinking water, there are now data for about 36 metals from one analysis.

The availability of all these extra data arises from a combination of more efficient analytical techniques and a much greater sensitivity of detection. It does not follow, though it is sometimes thought to be the case, that drinking water, for example, is being contaminated with increasing numbers of metals. Rather that they were always there, but in recent times they can be detected and quantified. Thus, the presence of potentially toxic substances in very small amounts in drinking water or its additives, does not necessarily represent a danger to health. As with the corrosiveness of hydrofluorosilicic acid, discussed earlier, it is the final concentration of any toxic metal after dilution and mixing of the additive that is important. If the final level of lead, for example, is 0.1 µg/l (microgram per litre; one-thousandth of a part per million) in drinking water then its presence poses no danger to human health, as this is only one per cent of the most stringent permissible limit for lead.

Another point worthy of consideration is that for most substances, and for any given species including humans, there is a relationship between concentration and toxicity – the more of a substance present the more likely it is to have ill-effects (if it is toxic). It is also true that some substances, which are toxic or greatly so – including arsenic and selenium – are also essential human metabolic requirements, the necessary quantities being provided by food, such as fruit and vegetables.

Therefore although many substances which can be harmful to humans in concentrated form are present in drinking water and come from a number of sources including the raw water supply and the water distribution system, the enormous dilution of these substances renders them harmless.

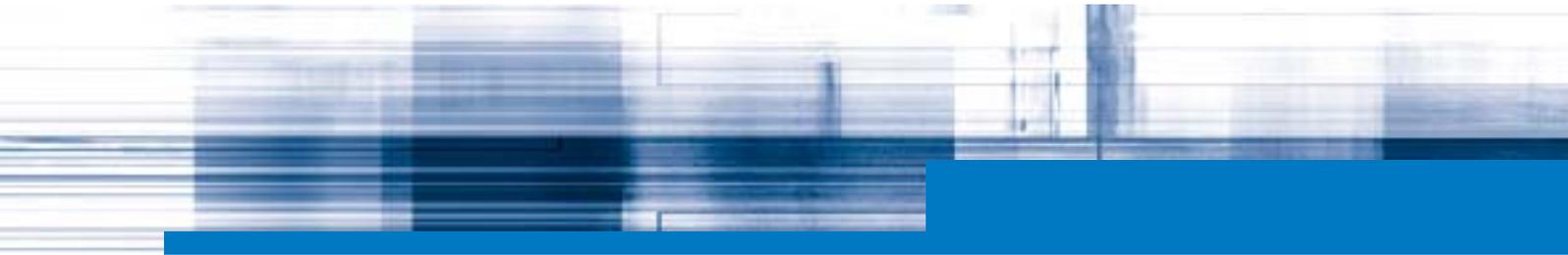
Objectionable Tastes in Water

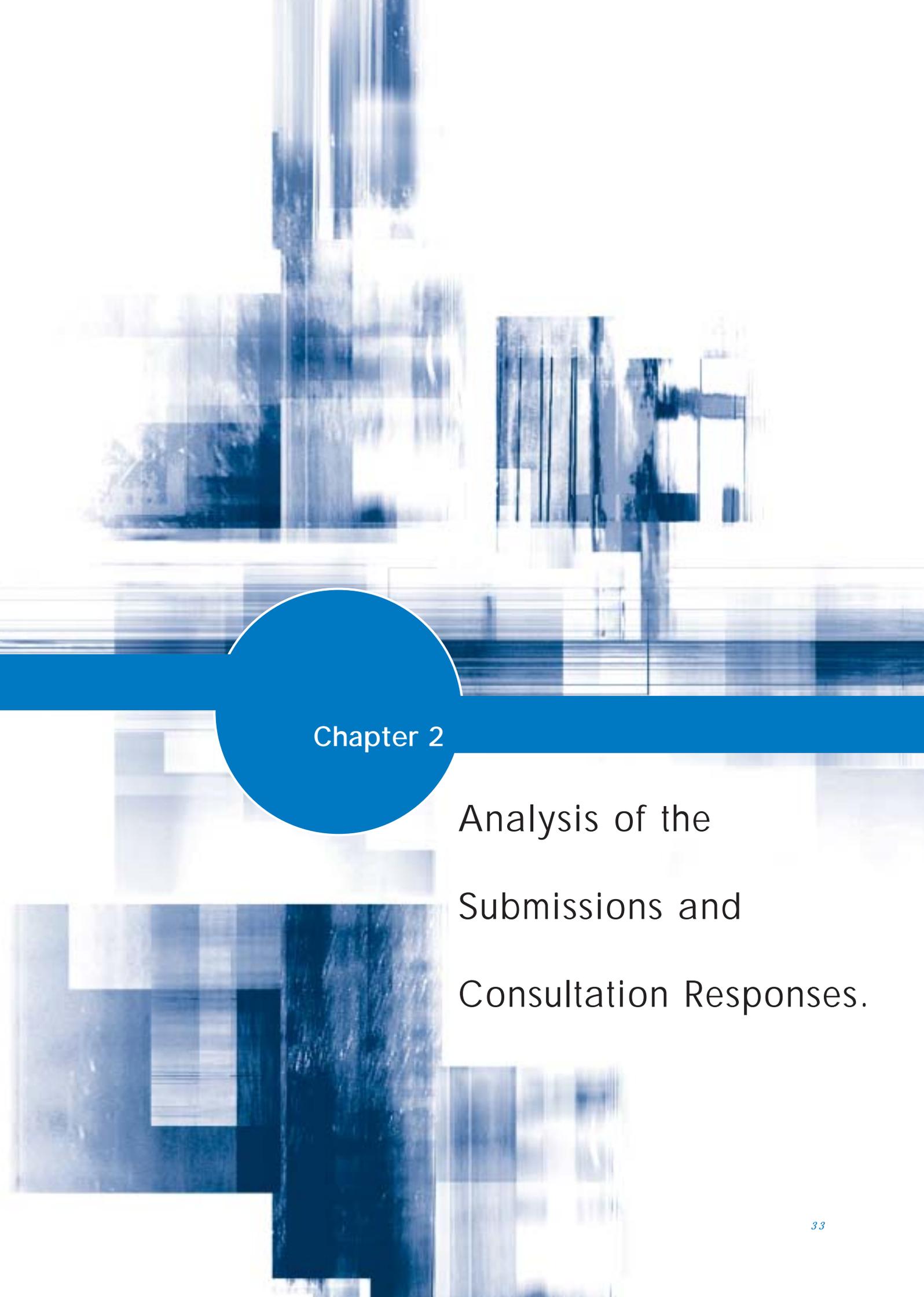
Fluorine is a member of the halogen group of substances, as is chlorine, and both feature in the treatment of drinking water. While there is debate – hence the Forum – about the desirability and/or necessity of adding fluorine (in the form of fluoride) to drinking water, there is no comparable situation regarding chlorine. It is added for the purpose of disinfecting so-called ‘raw’ water to make it suitable for drinking and its addition is without question the most important element in the safeguarding of the health of consumers. It is mentioned in the present context because the consultation process revealed that there is confusion between the two substances.

Over-chlorination of water or the need to respond to contamination incidents occurs occasionally in water supplies due to operational difficulties. While there are no direct health connotations of excess chlorine (people survive the high chlorine levels in swimming pools without problems), its presence manifests itself in a taste problem of greater or lesser severity – the water tastes of bleach. This problem lies beyond the remit of the Forum but it is mentioned because some respondents to the consultation have believed that the taste in their drinking water is a consequence of fluoridation. This is not the case. At all levels found in drinking water fluoride does not have a taste.

Conclusion

As mentioned, the substantive issues raised by the public consultation activity will be addressed in the appropriate chapters below. Having discussed and put into perspective some of the erroneous beliefs shown up by the consultation, the following chapter reveals its major findings.





Chapter 2

Analysis of the
Submissions and
Consultation Responses.

Analysis of the Submissions and Consultation Responses

Introduction

It must be understood that this consultation exercise consisting, as explained, of an open invitation to the members of the public to submit their views, was not a scientifically designed and controlled survey in which the sampling was ensured to be random, as in a professionally executed poll. The consultation respondents cannot, therefore, be regarded as a representative sample of the Irish population. The format chosen was adopted for various reasons. Firstly, the time constraints were unavoidable; secondly, it was desired to leave action entirely to the discretion of the public; and, thirdly, the Dental Health Foundation, Ireland had already commissioned a rigorously controlled survey from Drury Research, Dublin, as discussed below.

Several respondents expressed the view that the comment form should have been delivered to every household in the country, a suggestion which was simply impossible to implement for practical reasons. The approach to eliciting responses from the public was both reasonable and acceptable, as evidenced by the volume of responses received and from the wide spread of geographical locations from which they came (Appendix 3).

It is quite possible, if not probable, that because the initiative was left to the public as regards the making of submissions, there is an element of bias in the pattern of responses received by the Forum. Clearly, many of the respondents felt deeply about fluoridation, or its implications, and were thus more likely to submit their views than perhaps those less committed or not as knowledgeable. However, the public as a whole were free to comment to the Forum, which must necessarily consider the submissions actually made.

In all, 1,046 individual responses were received by the secretariat. Although some 90 per cent of the respondents used the comment form (the remainder consisting of e-mails, letters etc), there was far less standardisation among responses than might at first be expected. In the case of the key first section (approval or disapproval of fluoridation of water supplies), for example, the answers were brief, unambiguous and easily analysed. However, the form was deliberately designed to seek the views and opinions of respondents, which consequently resulted in highly individual submissions, sometimes extensive. There was a substantial and a welcome expression of views and opinions, but this meant that the assessment of responses was not a straightforward matter.

The Findings of the Consultation

The following is a concise presentation of the outcome of the public consultation, the detailed results being presented in depth in Appendix 4.

1. I approve/do not approve of the fluoridation of drinking water supplies.

Approval	8.6%	Disapproval	89.0%	No View	2.4%
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2. I would approve/not approve of an alternative method of providing fluoride.

Approval	29.2%	Disapproval	50.5%	No View	20.4%
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3. I consider the benefits of fluoridation to be as follows:

Positive Comment	31%	Negative Comment	45%
Inapplicable Comment	1%	No Comment	23%

4. I consider the ill effects of fluoridation to be as follows:

Comment under this heading	85.4%
No Comment under this heading	14.6%

The comments referred in the main to perceived actual/possible/potential conditions attributable to fluoridation of drinking water supplies.

5. My concerns/views about the addition of fluoride to drinking water are:

See under Section 7 below.

6. I/my family/my children regularly use toothpaste containing fluoride Yes / No

'Yes' replies	464	'No' replies	427	Non-indicative replies	155
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7. I have the following additional remarks to make to the Forum:

The responses under these headings 5 and 7 were combined for analysis because of the overlapping manner in which many responses were presented. Each individual submission was examined and the points raised or themes arising from it noted. This scrutiny identified the following matters as those most exercising the minds of respondents. They are listed simply in alphabetical order below, but much further information is presented in Appendix 4.

Principal Issues/Themes arising from Consultation Submissions

These issues are arranged in alphabetical order.

Adverse reaction to exposure of population to perceived toxic additive
Banning/non-use of fluoride in other European countries in contrast to Ireland
Comments approving of and/or advocating continuation of fluoridation
Concern over financial/other hardship which limits/rules out bottled water
Concern over perceived or possible ill-effects on health of people/nation
Concern over reported contaminants of fluoride used: arsenic, lead etc
Concern regarding possible overdosing due to fluoride in water and food and toothpaste
Concern regarding the difficulty for some of avoiding the use of fluoridated drinking water (FDW)
Concerns and worries over possible long-term ill effects of fluoride
Concerns of varying gravity about the large fluoride discharges to environment
Concerns/doubts over fluoride dosing techniques by sanitary authorities
Consumers'/citizens' lack of choice in the matter of ingesting fluoride
Criticism of breaches of rights/unethical-immoral-illegal act of fluoridation
Desirability of application of Precautionary Principle
Dissatisfaction with government in various fluoridation-related matters
Objections to fluoridation without consent of the population
Expression of need for and concern over possible lack of careful monitoring
Failure of government to carry out health effects study (as per 1960 Act)
General concerns about the lack of information for the public on fluoride
Mistaken belief that fluoride used is waste product of fertiliser industry
Opposition to perceived enforced mass medication of population
Perceived need to use water filters; inapplicability of most to fluoride
Positive expressions that fluoridation should be halted
Specific concern of excess fluoride dose to infants with feed made up with FDW
Statement that there are no proven benefits of fluoridation
View that access to natural potable water is a human right, which is violated
View that fluoridation is unnecessary per se, or because of alternatives
View that if ill effects are proven there will be consequential litigation
View that personal intake of fluoride is effectively uncontrollable in reality.

The results of the consultation may be found in Appendix 4 where the findings on each section of the comment form are tabulated.

Conclusions from Submissions

Despite its inherent limitations and those imposed by time constraints, the consultation process was a very successful exercise of the Forum's mandate on Public Consultation.

Some one thousand individual responses were received from members of the public, representing a rather greater number of opinions in that some replies reflected the views of families or groups of people in a community.

The consultation process provided invaluable although not definitive or exhaustive opinions on the several points referred to the public. Clearly, among some of the respondents there is great opposition to the fluoridation of drinking water supplies; resentment and anger at what is perceived as an exercise in 'mass medication', which is regarded widely as an unwarranted intrusion by the State into the freedom of the individual and a breach of civil and human rights; anger also at the lack of choice in the matter of introducing additives to drinking water, appreciation of the value and importance of which was expressed repeatedly in the responses; and – of the greatest significance – a widespread fear of the perceived health effects, current and long-term, of fluoridation. Thus, the consultation responses constitute a most important input to the overall deliberations of the Forum.

Survey of Public Opinion

The Forum has had access to a report by Drury Research, Dublin of a survey of public opinion on fluoridation, commissioned by the Dental Health Foundation, Ireland.²

This was a wide-ranging professionally-designed survey of a random population sample which was carried out by Drury Research in September/October 2000 and covered 1,180 persons aged 15 years and upwards. The questionnaire used in the survey dealt with very much the same ground as the public consultation form used by the Forum but it was much more detailed in its coverage.

There is, accordingly, a much greater body of data available from the Drury survey than from the Forum consultation and for considerations of space but, more importantly, because of the structural differences between the two exercises it is not practicable to draw detailed comparisons between the two. However, some of the salient points established by Drury Research should be mentioned in brief:

- The question of fluoride in water is not a high level public concern, pollution being a much greater consideration.
- Overall, 45 per cent of people were either 'very concerned' (23%) or 'fairly concerned' (22%) about fluoride in water. The 35-49 and 50-64 age groups showed the greatest level of concern over fluoride.
- However, almost one-third of those whose domestic water contains fluoride are very concerned.
- Over five-sixths of people have heard of fluoride, to almost an identical extent from newspapers, radio and television.

- Similar numbers of people (40%±) believe that fluoride is added to water either to purify it or to prevent tooth decay. The remaining people are unaware of its purpose.

The level of concern which the public experienced with regard to fluoride and how this concern compared with concern for a range of other issues is illustrated in Appendix 5.

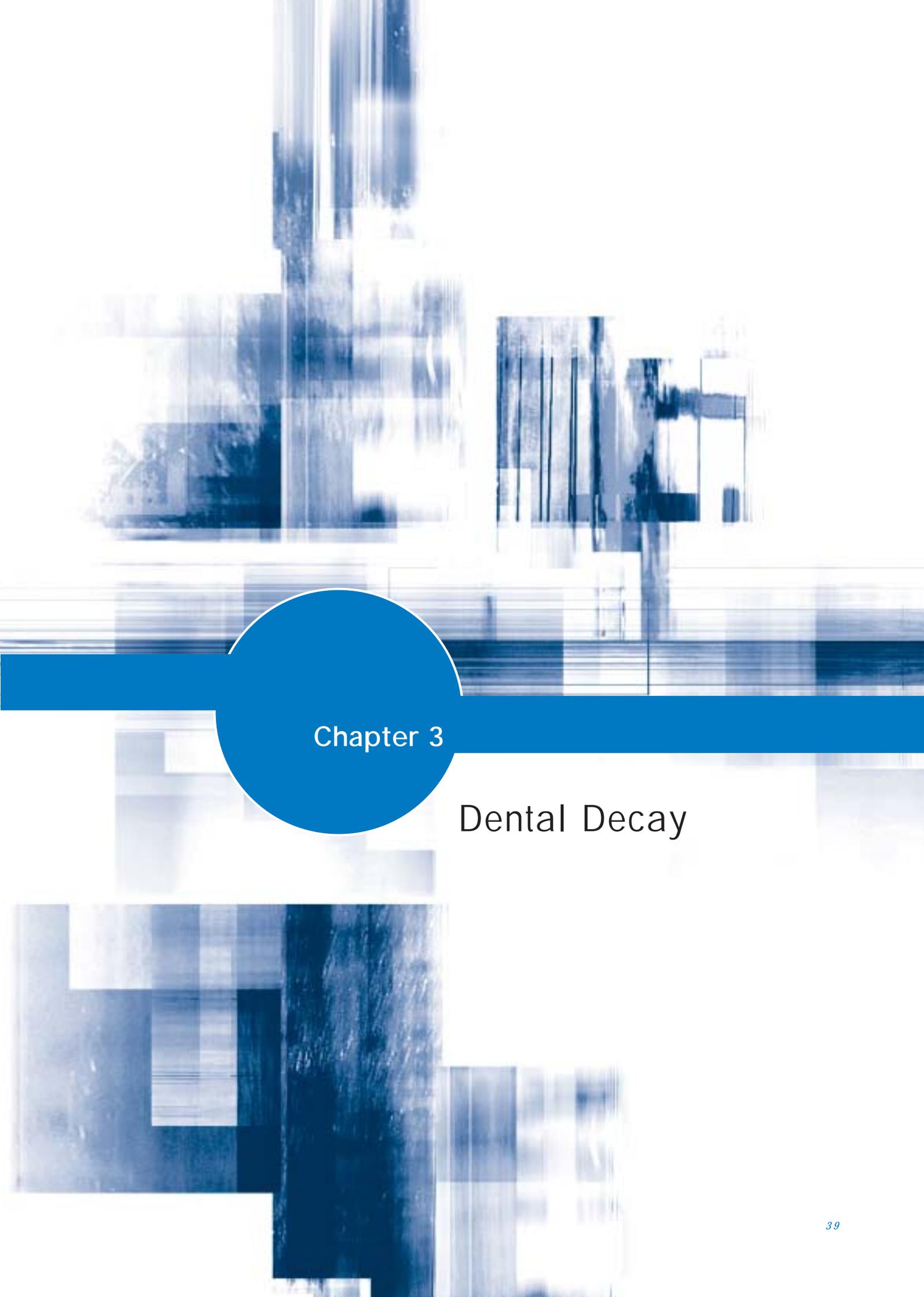
These findings show that among the population as a whole there is a modest level of concern about fluoride in drinking water, and that fluoridation is not a major issue. The Forum consultation shows a far greater level of concern over fluoridation – a finding that reflects the fact that respondents to the Forum, whether in favour of fluoride or otherwise, were either concerned and/or knowledgeable about the topic and wished to make their views known.

Two comments may be added. First, if there were greater awareness among the public as to the actual purpose of fluoridation, the pattern of responses to the Drury questionnaire might well have been different. Second, from a parallel scrutiny of the responses under headings 1, 2 and 3 of the consultation form it seems reasonable to infer that a significant (though not quantifiable) element of the opposition to fluoridation results not so much from opposition to fluoride *per se* as from dissatisfaction with procedural aspects of fluoridation such as lack of choice in the matter.

Views of Individual Local Authorities, Health Boards and Professional Bodies

Submissions were received from a number of health boards, local authorities and professional bodies. In the main they were broadly supportive of the continued fluoridation of water, with several calling for continued research and monitoring to be carried out. In a few instances, most notably the submissions from Killarney Urban District Council and Foyle Basin Local Authority in Northern Ireland, the continuation of fluoridation was opposed but little supporting evidence was given for the view. The Irish Women's Environmental Network also opposed fluoridation.

A full list of the bodies along with the summaries of their submissions is available in Appendix 6.



Chapter 3

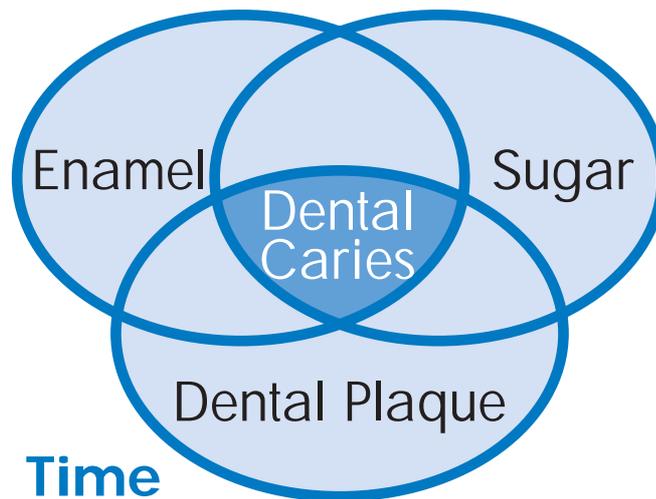
Dental Decay

3 Dental Decay

Introduction

Dental decay or dental caries is an infectious disease that affects most people in developed countries. There are many factors involved in the development of dental decay, the main factors being shown in Figure 1.

Figure 1: Diagrammatic representation of the four factors involved in dental decay: tooth enamel, plaque, sugar and time



The bacteria in dental plaque combine with the sugar; the plaque acids formed from this combination attack the tooth enamel resulting in the destruction of the tooth. If this happens often enough over time the surface of the tooth will eventually break down and a cavity will be formed. If sugar is consumed frequently throughout the day over many days, weeks and months, and if plaque control by tooth brushing and other means is not adequate, high levels of dental decay are more likely to occur.

Dental decay is sometimes described as a dynamic process with demineralisation (decay formation) happening alongside remineralisation (tooth repair). When the balance tips in favour of demineralisation through prolonged periods of frequent consumption of sugary foods combined with poor oral hygiene, cavity formation results. When the balance tips in favour of remineralisation (tooth repair), through reduced frequency of sugary foods and

better oral hygiene including availability of fluoride in the saliva, cavity formation is arrested or repaired.

The following photographs show normal teeth and decayed teeth.



Fluoride works to control dental decay in several ways and this will be described in detail in Chapter 4. The following is a brief summary of how fluoride prevents dental decay.

Fluoride slows down the pace at which minerals are removed from enamel when attacked by acid (demineralisation) following ingestion of food and drinks sweetened with sugar. It also helps to restore the lost mineral (remineralisation) when the acid attack is over. Fluoride also inhibits the process by which the bacteria produce acids. A key to the control of decay by fluoride is the maintenance of a low constant level of fluoride in saliva.

Burden of Illness from Dental Decay

The total annual non-capital spending on primary care dental services in Ireland is estimated to be in the region of €127 million. Over €100 million of this is spent on treating the effects of dental decay.

People of all ages who have their own teeth are potentially susceptible to dental decay. Because the health of teeth and supporting tissues has generally been improving, more adults are keeping their teeth longer. This is clearly an important health gain.³

Children are particularly vulnerable to tooth decay, notably during the first years following the eruption of teeth. In 1992, of the 250,000 national school children who were screened in this country by the community dental services, 171,000 received fillings and 98,000 received extractions.

As the average filling will not last indefinitely it is clear that if childhood prevention does not work, the adult is committed to a lifetime of fillings and re-fillings.

Certain members of society, as a result of either physical or intellectual disability, are unable to look after their teeth and regularly require extensive dental treatments. Due to their disabilities these treatments quite often require the use of general anaesthesia, which is never without risk. There is a small but significant mortality (death-rate) associated with dental treatment carried out under general anaesthesia in Ireland and the United Kingdom. In 2000, 4,300 children under 16 years of age received dental treatment under general anaesthesia.

Dental decay is a major cause of early loss of primary teeth, the consequences of which can be social, psychological and clinical. For instance, children and adults who later display anxiety about dental care are more likely to have had an extraction at their first visit to the dentist and found this a disturbing experience.

It can be difficult to obtain accurate information describing reasons for dental visits, because treatment and/or prevention of carious lesions is one of several possible reasons for visiting a dentist. A national survey of Oral Health in Irish Adults found that although the majority of Irish adults were aware that regular attendance at the dentist was desirable only a third did, in fact, regularly attend a dentist.⁴ Data from the US Surgeon General's report on oral health revealed a clear picture of differences in the receipt of oral health care by race, ethnicity, income and insurance status.⁵ Among white, non-Hispanic adults, 64 per cent reported a dental visit in 1993, compared to 47 per cent of Black, non-Hispanic adults and 46 per cent of Hispanic adults. For individuals at or above the poverty level, 64 per cent reported a dental visit in the previous year, compared to 36 per cent for those with incomes below the poverty level.

In Ireland during 1999 approximately 155,000 medical card patients had 215,000 fillings and 90,000 extractions.

Over and above the substantial economic costs of dental care, the costs associated with loss of working time and earnings, missed school and reduced levels of social functioning must be taken into account.

The US National Health Interview Survey (NHIS) indicated that 2.9 million acute dental conditions occurred among the US population during 1994. These conditions accounted for an estimated 3.9 million days of missed work among persons 18 years of age and over, 1.2 million days of missed school among youths aged 5 to 17 years and 12.2 million days of restricted activity across all ages.⁶ Poor children suffer nearly 12 times more restricted-activity days than children from higher income families. Among low-income families, almost 50 per cent of tooth decay remains untreated.⁵

The physical effects of dental decay are experienced in both the short term and the long term. In the short term, discomfort and pain are the most likely consequences of untreated lesions. Physical impacts can be felt directly through the pain of toothaches, and loss of function, resulting in part from a loss of back teeth and failure to replace them when necessary. The possible eventual reduced eating capacity, e.g. to bite and chew, due to tooth loss can lead to unnecessary dietary restrictions and nutritional deficiencies as well as complicate the dietary management of other chronic health conditions.⁷

The psychological pain of self-consciousness and social isolation may also accompany the embarrassment of the unsightly deterioration of front teeth caused by dental decay. The same psychological distress can result from the embarrassment of missing front teeth, the communication problems associated with not being easily understood by others, and the isolation or withdrawal from social intercourse because of missing teeth.

In the longterm, untreated carious lesions may lead to the loss of such teeth, the replacement of which may be needed for functional, social, cosmetic, and physical and mental health reasons.

In conclusion it can be seen that dental decay has a broad impact on many aspects of the quality of life and its prevention is therefore very important.

Tooth Development

It is important to appreciate the timing of the development of both baby and permanent teeth. Development of the baby teeth (deciduous dentition) commences in the womb. There are 20 baby teeth, all of which are usually visible in the mouth by about 2 years. There are 32 permanent teeth. As can be seen calcification of the primary (deciduous) teeth commences as early as the 3rd-6th month of pregnancy.⁸ The development of the permanent dentition (adult teeth) is summarised in Tables 3.1 and 3.2 below.⁸ Calcification of some permanent teeth commences as early as the time of birth and of others at 3-4 months of age. All times given in these tables are averages; there can be considerable variations.

Table 3.1 Primary Teeth Chronology				
	Incisors	Canines	1st Molars	2nd Molars
Calcification commences	3rd-5th month in utero	5th month in utero	5th month in utero	6th-7th month in utero
Completion of crown	Age 4-5 months	Age 9 months	Age 6 months	Age 10-12 months
Appearance in mouth	Age 6-8 months	Age 16 -20 months	Age 12-16 months	Age 21-30 months

Table 3.2 Permanent Teeth Chronology								
	Central Incisors		Lateral Incisors		Canines		First Molars	
	U	L	U	L	U	L	U	L
Calcification Commences	3-4m	3-4m	10-12m	3-4m	4-5m	4-5m	Birth	Birth
Completion of crown	4-5y	4-5y	4-5y	4-5y	6-7y	6-7y	2.5-3y	2.5-3y
Appearance in mouth	7-8y	6-7y	8-9y	7-8y	11-12y	9-10y	6-7y	6-7y

U = upper jaw L = lower jaw m = months y = years

Measurement of Dental Decay

The most widely used method of measuring dental decay is to count the number of decayed, missing and filled teeth (DMFT) and this has become known as the DMFT index. This is usually attributed to Klein, Palmer and Knutson in their studies of dental decay in Hagerstown, Maryland in the 1930s.⁹ Since then, the index has received almost universal acceptance and is probably the best known of all dental indices.

A person's score on the index is irreversible in that once decay occurs in a tooth it cannot be reversed. The score ranges from 0 to 32 and applies to permanent (adult) teeth only. If a person has three decayed teeth, which have not been treated, two filled teeth, and one tooth extracted as a result of decay, his or her DMFT score is six. If the three decayed teeth are later treated by fillings the DMFT score remains six as the number of filled teeth will rise to five and the number of decayed teeth will become zero.

The DMF index can be applied to whole teeth (designated by **DMFT**) or to surfaces (**DMFS**). Uppercase (capital) letters always signify the DMF index for permanent teeth. Lower case letters are used for primary teeth. The equivalent for the 'm' stands for extraction due to caries and 'f' for filled.

Risk Factors for Dental Decay

Caution is necessary when interpreting data on the oral health status of different populations; variations in the diagnostic methods used during the course of oral health surveys will affect the results. When comparing decay experience both between and within countries over time, the contribution of a complex array of factors must be taken into

account. Changes in the distribution of decay within the mouth together with changes in decay management techniques, health funding and access to dental care have occurred in many developed countries over the last few decades.

Other factors which may influence oral health include changes in dietary habits, changes in the pattern of sugar consumption, possible changes over time in saliva properties, the use of antibiotics or other medicines which may cause changes in the amount, composition or virulence of the oral micro-organisms, the use of fissure sealants and the use of restorative materials which release fluoride.

Predicting who will develop dental decay is an inexact and developing science.¹⁰ Decay risk assessment is difficult because it attempts to account for the complex interaction of multiple factors. Although various methods for assessing risk exist, no single model predominates in this emerging science.

Groups believed to be at increased risk for dental decay are those with low socio-economic status or low levels of parental education, those who do not seek regular dental care, those with limited access to fluoride and those without access to dental services.

Persons can be at high risk even if they do not have these recognised factors. Individual factors that possibly increase risk include active dental decay, a history of high decay in the family, malformed enamel or dentin (the part of the tooth under the enamel), reduced salivary flow due to medication or disease, and the wearing of space maintainers, orthodontic appliances such as braces or dental prostheses such as false teeth, crowns, or bridges.

Risk can increase if any of these factors are combined with dietary practices conducive to dental decay. Risk decreases with adequate exposure to fluoride.

Sugar Consumption

In Ireland for the period 1963 to 1979 annual sugar consumption rates were approximately 46 kg per person per year, declining to approximately 40 kg per person per year between 1986 and 1988. Between 1989 and 1993 a further decline to approximately 37 kg per person per year was seen.¹¹

These figures should be looked at in the context of dietary habits in general. Data from the Health Behaviour in School Children Report found that of all the countries surveyed the percentages of students who reported eating sweets or chocolate every day was consistently the highest in Northern Ireland (73-81%), Scotland (71-78%), and Ireland (71-80%).¹² The percentage in Finland was the lowest (12-24%).

The consumption of soft drinks has increased considerably in recent years. Levels of consumption are over 50 per cent greater than in 1988. Fruit flavoured drinks are particularly popular with young children. They are often regarded as healthier alternatives to fizzy drinks, due to their fruit and vitamin content.

However, studies show that they contain similar sugar levels to many fizzy drinks and most are highly acidic, which is also detrimental to dental health.

In 1999, the National Nutrition Surveillance Centre in the National University of Ireland in Galway studied the dietary habits of the Irish population.¹³ It was found that there was a significant variation in the quantities of fizzy drinks consumed daily across all social classes. The younger age group, lower socio-economic groups, urban dwellers and those living with others consumed greater quantities than their counterparts. Urban dwellers consumed significantly greater amounts of low calorie fizzy drinks compared to other groups. While these low calorie drinks have a lower sugar content, they are, however, just as acidic as the ordinary fizzy drinks and may cause erosion of tooth enamel.¹⁴

Prevalence of Dental Decay

Although the prevalence of dental decay in children has declined markedly over the last 20 years in most countries in the Western world, the disease continues to be a major problem for both adults and children everywhere. The trends in decay in US children during the last 30 years were recently summarised on the basis of results of four national surveys.

It was shown that while over 50 per cent of children (aged 5 to 17 years) were decay-free, when the 12 to 17 year olds were looked at, approximately 70 per cent still had decayed teeth.

These decreases in decay prevalence and severity have been uneven across the general population; the burden of disease now is concentrated among certain groups and persons. For example, 80 per cent of the dental decay in the permanent teeth of US children aged 5 to 17 years occurs among just 25 per cent of those children.¹⁵

Dental Caries Surveys in Ireland

The Medical Research Council conducted the first survey of children's dental health in Ireland in 1952. The examiners were trained by personnel from the Department of Health in London in order to make sure that the data collected in Ireland and the UK would be comparable.

This level of collaboration in monitoring dental decay levels in Ireland and the UK has been maintained since that time; hence comparisons between current decay data in the Republic of Ireland can be validly compared with those collected in the UK. The second national survey of decay levels in Ireland was conducted in 1962 when, under Section 2 (4)(a)(1) of the Health (Fluoridation of Water Supplies) Act, 1960, the prevalence of dental decay in each county in Ireland was measured (see Appendix 7).

Following the introduction of water fluoridation in Dublin in 1964, in Cork in 1965, and in the remaining major urban communities over the subsequent five years, local studies were

conducted to monitor the effectiveness of water fluoridation. These studies indicated that subjects residing in fluoridated communities had better dental health than those residing in non-fluoridated communities.⁵⁸

The next national survey of children's dental health was conducted in 1984. Random samples of children were examined using the same criteria as those used in earlier studies. Approximately 80 per cent of all decay occurred in just 20 per cent of the children.^{16, 17} An important public health question is the identification of this high-risk sub-group. There is evidence to show that this 20 per cent is largely comprised of less well-off sections of the population. It was found that decay levels had declined between 1961-1963 and 1984, this decline being greatest in those children who had been lifetime residents of fluoridated communities. Because children residing in non-fluoridated communities in the Republic of Ireland had access to products made from fluoridated water and also because some children resident in non-fluoridated communities occasionally spent time in fluoridated communities it was clear that the non-fluoridated group in the Republic of Ireland did not represent a true control group for comparison purposes (this is known as the 'halo effect', which results from exposure to sources of fluoride in foods and drinks produced in fluoridated areas).

It could be argued that a reasonable control group would be residents of Northern Ireland where water supplies are not fluoridated and where, as in the Republic of Ireland, fluoride toothpaste was introduced in the early 1970s.¹⁷

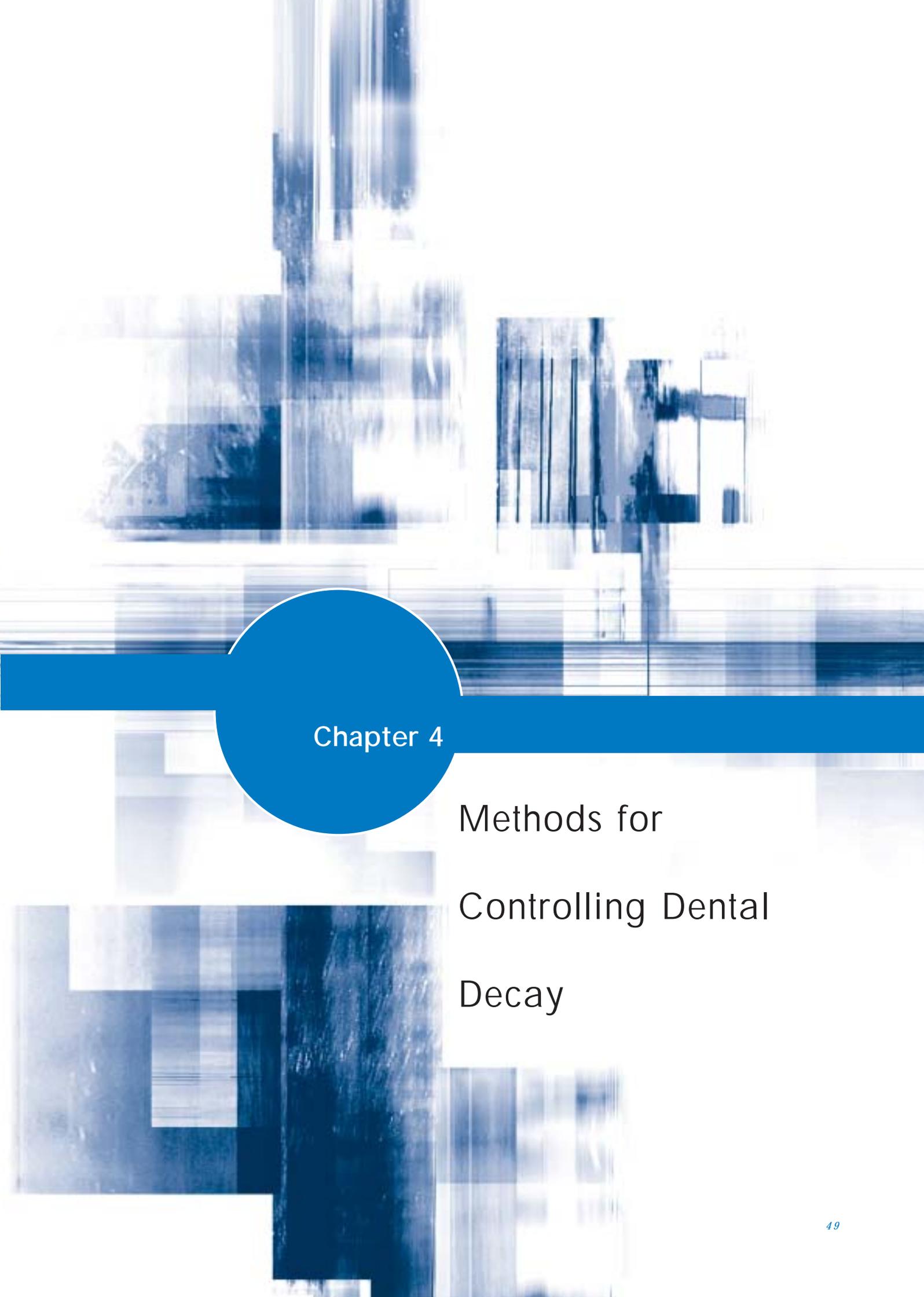
During 1963 a representative sample of schoolchildren in Belfast was examined for dental decay using criteria similar to those being used in Britain at the time and similar to those adopted in the pre-fluoridation baseline surveys in the Republic of Ireland in 1961-63. In 1983 a survey of children's dental health in the United Kingdom included an examination of a representative sample of children in Northern Ireland. The results of these surveys can be seen in Table 3.3 below. It can be seen in 1963 that the mean DMFT amongst 8,12 and 15 year olds in Northern Ireland was similar to that in the Republic of Ireland. Water fluoridation was introduced in the Republic of Ireland in 1964. Fluoride toothpaste was introduced in Northern Ireland and in the Republic of Ireland at the same time in the early 1970s. In 1983 the mean DMFT amongst 8,12 and 15 year olds in Northern Ireland was 1.5, 4.4 and 8.5 respectively. The corresponding figures in 1984 in the Republic of Ireland for life-time residents of fluoridated communities was 0.6, 2.6 and 4.1. Recent data indicate that children and teenagers who are life-time residents of fluoridated communities in the Republic of Ireland (e.g. North Western Health Board) continue to experience considerably lower levels of dental decay than their counterparts in Northern Ireland. It is possible that various sociological, dietary and other factors account for part of this difference but it is reasonable to suggest that the major contributing factor is the fluoridation of public water supplies.

Age	Northern Ireland		Republic of Ireland	
	Mean DMFT		Mean DMFT	
	1963	1983	1961-63	1984 (full fluoridation)
8	2.0	1.5	1.7	0.6
12	5.5	4.4	4.7	2.6
15	9.4	8.5	8.2	4.1

During the 1990s, the health boards monitored the effectiveness of water fluoridation. These have shown that people who have resided in fluoridated communities continue to experience lower levels of dental decay than those resident in non-fluoridated communities. This benefit is evident among both children and adults.

Currently, a national survey of adult dental health, which began in April 2001, is nearing completion. One of the main aims of this study is to measure the effectiveness of water fluoridation in adults and to monitor changes in the oral health of adults in different social groups in Ireland.

In October 2001 a further national survey of children's dental health was initiated. Again, one of the main aims of this survey, in which 14,000 children will be examined, is to measure the effectiveness of water fluoridation. This project and the surveys conducted in the 1980s and 1990s also include measurement of the levels of dental fluorosis in residents of fluoridated and non-fluoridated communities. A novel feature of this latest children's survey is the fact that children in Northern Ireland will also be examined using the same diagnostic criteria. As mentioned earlier, the water supplies in Northern Ireland are not fluoridated. A further innovation in this study is the use of a newly developed photographic technique in the measurement of dental fluorosis. An important advantage of this technique is the fact that photographed teeth may be assessed for fluorosis with the examiner not knowing the source of the photographs.



Chapter 4

Methods for Controlling Dental Decay

4 Methods for Controlling Dental Decay

Introduction

Over the years a number of strategies have been developed for the prevention and control of dental decay. These can be divided into those aimed at the community in general and those aimed at individual patients in dental clinics. This Report is mainly concerned with community approaches to prevention.

- Fluorides
- Fissure sealing
- Influencing dietary choice
- Plaque control
- Regular professional care
- Other strategies, e.g. natural defences

It is worth noting that in many communities combinations of the above strategies are deployed. Three of the strategies, namely influencing dietary choice, plaque control and regular dental visits, involve public compliance and these are the main messages of dental health education programmes.

Fluorides

Following the discovery that fluoride in drinking water had dental decay preventive properties the use of other forms of fluoride delivery have been investigated for over 60 years. A classification of fluoride products and vehicles used in dental decay prevention is as follows:

Home/School use

Drinking water

Drops

Tablets

Salt

Milk

Sugar

Mouth rinses

Toothpastes

Applied Professionally in Dental Clinic

Gels

Varnishes

Slow release devices and products

Water Fluoridation

A review of water fluoridation is the remit of the Forum and is dealt with in detail throughout the course of this Report.

Salt Fluoridation

The addition of fluoride to salt as a means of preventing dental decay has been used in a number of countries since the 1950s. Generally 200 to 250 mg fluoride is added to each kilogram of salt. Most of the original research and epidemiological studies were initiated in Switzerland. Since that time salt fluoridation has been used in Costa Rica, Jamaica, Germany, Spain, Austria, Belgium, Czech Republic and France and, more recently, in a number of South American countries. The current status of salt fluoridation in the South American continent is presented in Table 4.1 below.¹⁸

Table 4.1 Salt fluoridation in South America	
Country	National Salt Fluoridation Programme
Belize	In progress
Bolivia	Yes
Colombia	Yes
Costa Rica	Yes
Cuba	In progress
Dominican Republic	In progress
Ecuador	Yes
Grenada	Projected
Guatemala	In progress
Guyana	Projected
Honduras	In progress
Jamaica	Yes
Mexico	Yes
Nicaragua	In progress
Panama	Yes
Paraguay	Yes
Peru	Yes
Uruguay	Yes
Venezuela	Yes

The effectiveness of salt fluoridation has been monitored and a decrease in the incidence of dental decay has been shown in those subjects living in communities which consume fluoridated salt.

The World Health Organisation (WHO) has outlined certain requirements for the use of salt fluoridation:

- Low levels of fluoride in the domestic water supply
- Water fluoridation not technically or logistically possible
- Political will for introduction of fluoridated water not strong
- Good centralised salt production facility
- Strong technical support for the process.

Fluoridation of salt appears to be a reasonable alternative to water fluoridation in countries where the latter is not possible. However, nutrition policies in many countries advise a reduction in salt intake in order to prevent raised blood pressure and the associated cardiovascular diseases. The level of salt in the Irish diet is currently under review by the Nutrition Sub-Committee of the Food Safety Authority of Ireland.

Fluoridated Milk

Milk fluoridation schemes have been implemented in seven countries including, China, Chile, Russia, Bulgaria, Peru, Thailand and the UK. Several of the projects have recently been evaluated and the results have further highlighted the potential for using milk as a vehicle for fluoride, particularly in areas where it has not been possible to introduce water or salt fluoridation. Interest in this method of intervention continues to grow and proposals for the introduction of a number of new schemes are under consideration.

Schemes have been introduced through existing school and nutrition programmes. In Chile, a scheme was successfully implemented under a national nutrition initiative that involves the distribution of milk products through health clinics for children from the age of six months to six years.¹⁹ Most other schemes have been school based although in Peru, a government programme providing milk for children up to the age of six, through a well established network of community centres, has been utilised.

In the UK, milk fluoridation was first introduced in 1993.²⁰ There are currently seven districts involved in the programme, including schemes recently introduced in Greater Manchester. The programme is reaching children living in communities that suffer some of the highest rates of dental disease in the country.

Fluoridated Sugar

A study group was formed in 1989 by the Oral Health Programme of WHO, Geneva, to consider the possibility of reducing dental decay by adding fluoride to sugar. The outcome

of this exercise was the setting up of a series of studies in order to establish the feasibility of adding fluoride to sugar in dental decay preventive programmes. The deliberations of the working groups and the results of the studies undertaken were published in a series of articles in *Advances in Dental Research* in February 1995.²¹

There is convincing laboratory evidence to show that adding fluoride to sugar reduces the decaying effects of sugar and sugar products on teeth.²²⁻²⁴ However, further studies are required before its potential as a public health measure can be assessed.

Fluoride Supplements

Fluoride tablets/drops were introduced originally as an alternative to water fluoridation in non-fluoridated areas and have been used both on a community basis and for individuals. The original dosage schedule was too high and resulted in excessive intake of fluoride and higher rates of dental fluorosis. More recent schedules limit the use of fluoride tablets to individuals in low fluoride areas and to children over three years of age. The effectiveness of supplements has been inconsistent as compliance with the schedule is challenging.

Generally, the use of fluoride supplements on a community basis has ceased. On an individual basis they are used as follows:

- High risk individuals
- Over 3 years of age
- Low fluoride area
- Chewed/sucked slowly
- Using an appropriate dosage schedule

Fluoride Toothpastes

Fluoride toothpastes were first introduced to Ireland in 1970. The most common level of fluoride in such toothpastes is 1,000/1,200 ppm (parts per million). There is an EU guideline which states that fluoride toothpastes sold over the counter should contain no more than 1,500 ppm fluoride. Over the last ten years there has been increasing concern about the fact that infants and very young children tend to swallow fluoride toothpaste and there is good evidence to show that this has contributed to an increased level of dental fluorosis.

As a result paediatric toothpastes (some containing approximately 500 ppm fluoride) have been introduced. However, there is doubt as to the effectiveness of these paediatric toothpastes in the control of dental decay.

There is now convincing evidence that the effectiveness of fluoride toothpaste in the control of dental decay is increased by approximately 7-8 per cent for every 500 ppm fluoride added to fluoride toothpaste. In children less than 6 years of age it is recommended that only a small amount of paste is used and that children be supervised so that they do not swallow the paste.

There is considerable evidence to show that the widespread use of fluoride toothpaste has made a major contribution to the decline in dental decay now evident in most developed countries. Currently in Ireland over 95 per cent of the toothpastes sold contain fluoride. In 1994 it was estimated that toothpaste use in Ireland at 270 gm/person/year was somewhat lower than the average in other European countries. Recent studies show that combinations of water fluoridation and fluoride toothpastes give considerably greater benefit than either water fluoridation or fluoride toothpaste used alone.

Fluoride Mouth-Rinsing

Daily, weekly and fortnightly fluoride mouth-rinsing schemes have been used as public health and individual based programmes. These programmes have been shown to be effective.²⁵⁻²⁷ Currently in Ireland there are approximately 30,000 children in 500 schools participating in fortnightly mouth-rinsing programmes.

It has been shown that these mouth-rinsing programmes are almost as effective as water fluoridation. However, since they are school-based they are not effective in older age groups. Also the cost effectiveness of these programmes is questionable when compared with water fluoridation.²⁸

Professionally Applied Fluoride Products

Fluoride can be delivered in different formats to individuals, e.g. by dentists and dental hygienists. Various systems are used such as fluoride gels, fluoride varnish, fluoride rinses, slow release fluoride devices, etc. Their role is primarily limited to high risk individuals and special needs patients.

Fissure Sealing

For over 50 years, dental researchers have attempted to develop a technique to prevent dental decay in the pits and fissures of teeth. This research priority was based upon the fact that these surfaces are particularly prone to dental decay. Recent studies in Ireland indicate that, despite an overall decline in dental decay, pits and fissures continue to be particularly at risk from decay. Fissure sealants are particularly useful in communities where water fluoridation and other fluoride strategies are used because fluoride is not particularly effective in controlling dental decay in pits and fissures. A big advantage of fissure sealing is that the technique is non-invasive (no drilling) and the technique is acceptable to most children. When considering fissure sealing as a public health measure a major consideration is the cost effectiveness of the approach. It would be impractical and extremely costly to apply sealants to all pits and fissures of permanent teeth in Ireland. A major consideration is how to select those children who are at risk of developing decay in their pits and fissures. If this could be done then preventive programmes including fissure sealing could target these children.

Dietary Choice

There is unequivocal evidence to show that the frequent consumption of sugars is a major cause of dental decay. In Ireland the main sugar used is sucrose. The most recent figures indicate high consumption patterns in Ireland at 37 kg/person/year and these figures have changed little over the last 20 years.

Indeed, there is evidence to show that the dietary patterns in Ireland at present are more harmful to dental health than they were 20 years ago. Many people, including children and adults, engage in almost ongoing consumption of foods and drinks sweetened with sugar throughout the day.

Dental health education programmes which include among their aims the reduction in the frequency of consumption of foods and drinks sweetened with sugar have had little success.²⁹

Recent data on Irish dietary habits reveal that the consumption of sugary foods and drinks is alarmingly high in the Irish population.¹³ The amounts in a number of foods and beverages consumed per day are shown in Table 4.2 below.

Food / Beverages	No. persons	Average amount consumed per day
Cakes and biscuits	5,153	48 g
Dairy desserts	4,924	33 g
Confectionary	5,300	33 g
Fizzy drinks	2,803	127 g
Low calorie fizzy drinks	2,338	133 g
Juices	4,228	110 g

It should be noted that while low calorie fizzy drinks may be low in sugar, they are equally acidic as the regular varieties and as a result have a similar potential to cause erosion of the teeth. Most cartons of ready-to-drink fruit drinks are high in sugar. One glass can contain the equivalent of 5.5 teaspoons of sugar (27 gms).

The consumption of foods and drinks has been studied as part of the European Health Behaviour in School Children Study.¹² It was found that over 60 per cent of boys aged 12 to 14 years consumed high fat and high sugar foods frequently during the day; approximately 50 per cent of children under 12 years and over 14 years of age were found to consume similar amounts. This was most marked in the lower socio-economic groups, which have also been shown to have higher levels of dental decay.

The frequency of consumption of these foods and beverages are shown in Table 4.3 below.

Table 4.3 Frequency of Consumption of Selected Foods or Drink; Europe		
Foods/beverages	More than once a day, %	Once a day, %
Coke or other soft drinks containing sugar	38	26
Sweets (candy or chocolate)	41	36
Cakes and pastries	8	14
Low fat milk	21	13
Whole milk	37	20

Milk is being displaced from the diet of many children and teenagers by soft drinks and juices. Apart from the effect on dental health of the sugars and acidity, the diet is also becoming deficient in calcium and this may result in osteoporosis in later years.

Plaque Control

The combination of dental plaque and sugar leads to an increase in the acidity of plaque fluid, which causes demineralisation of the enamel. If this happens regularly over an extended period of time a tooth cavity will result. Hence, programmes and techniques designed to reduce plaque accumulation and aid plaque removal have been to the forefront of dental health education programmes for many years.

The most widely used method for plaque removal in developed countries is tooth-brushing and there is evidence that toothbrush sales in Ireland have increased in recent years. However, for most people tooth-brushing is a rather inefficient way of removing plaque and if sugar consumption continues unaltered in frequency there will be sufficient plaque left for

decay to occur. The advent of fluoride toothpastes however has altered this balance. The main purpose of tooth brushing now in the control of dental decay is that it acts as a vehicle for introducing fluoride into the oral cavity. Hence, it is not the plaque removal which is achieved by tooth brushing that contributes to decay reduction; it is the fact that the toothpaste contains fluoride. For individual patients other plaque removal techniques can be used such as interdental cleaners, dental floss and techniques such as chemical control, but these have questionable value in community programmes.

A number of recent systematic reviews of the effectiveness of dental health education programmes have concluded that the results of these programmes have been disappointing.^{29, 30}

Regular Professional Care

There is extensive evidence to show that persons who attend regularly for professional dental care will have improved dental health. Those who attend regularly have the benefit of individually focused preventive programmes and also the benefit of early diagnosis of decay and other diseases. It is interesting to note that the Finnish study presented by Seppa and Hausen to the Forum showed that when water fluoridation was withdrawn the level of professional care was increased.³¹ Similarly, many studies from Scandinavia have shown that deployment of many dentists and auxiliary dental workers will result in reduced levels of dental decay in the population. However, the cost of such an approach is very high.

Other Strategies

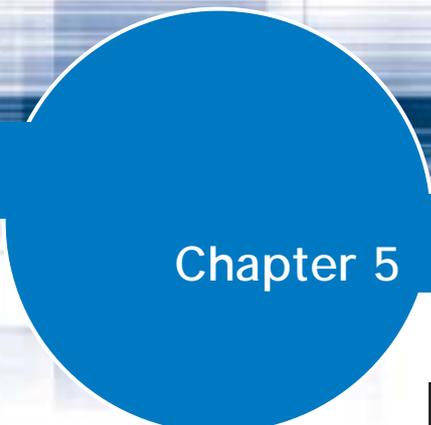
There are a number of other approaches which can be adopted for the control of dental decay. For example, it is well established that increased salivary flow can lead to a reduction in dental decay and in this regard the use of chewing gum has been shown to be effective in dental decay reduction. More recently the use of sugar-free gums has been shown to be more effective than sugar-containing gums. Hence, the use of sugar-free chewing gum is advised for subjects with high risk of dental decay.

Another approach which has been considered is the partial replacement of sugar in the diet with alternative sweeteners such as xylitol, sorbitol, mannitol and aspartame. There is evidence that the use of alternative sweeteners is increasing in Ireland.

Summary

At present the fluoridation of salt would appear to be the only realistic alternative to water fluoridation. When the salt for bakeries and other industries is fluoridated as well as

domestic salt, population coverage is virtually complete. However, there could be objections to its introduction because of the relationship between heart disease and dietary salt. Further research is required in the case of milk fluoridation. Fluoride toothpaste is an excellent adjunct to other forms of fluoride delivery systems aimed at communities. The remaining fluoride alternatives are expensive and resource intensive to deliver, not as effective as community systems, and involve compliance by the public. Attempts to change health behaviour are not always successful, especially in the more vulnerable sectors of society. Dietary and plaque control programmes on a community basis have not been shown to be effective.



Chapter 5

Provision of Oral
Health Care Services

Provision of Oral Health Care Services

Background

The organisation of oral health care in the European Union (EU) and in the European Economic Area (EEA) countries can be categorised under five broad headings.³² These are the Nordic, Bismarckian inspired, Beveridgian, Southern European, and Hybrid models.

Typical features of the Nordic model (found in Denmark, Finland, Norway and Sweden) are: a significant level of government involvement, a level of public funding equal to or nearly equal to private funding, a large number of dentists working in salaried employment for a public health service, free dentistry for those under the age of 19 years and some others in 'special' categories, and widespread use of dental hygienists and other clinical auxiliaries.

The Bismarckian inspired model (found in Austria, Belgium, France, Germany and Luxembourg) has its roots in the principle of universal sickness insurance. In its current forms it covers oral health care and is operated by agencies which negotiate fees directly with dental associations, rather than with governments. Within this model the great majority of dentists work independently as private practitioners and the public sector is very small. Subsidised treatment is provided for most adults. Subsidies for the care of children are usually higher but some co-payment is required from all patients or parents. Dental hygienists or other clinical auxiliaries are rarely used.

The Beveridgian model is unique to the United Kingdom. It involves dentists working as independent 'private' practitioners (contractors) in a public system managed by the government. Free care is provided for children up to the age of 18 years and many 'special' groups of adults. Subsidised care is provided for all other adults. However, a private sector exists. There is widespread use of dental hygienists and a 'team' approach to dentistry.

The Southern European Model (found in Italy, Portugal, Spain and to some extent Greece) is predominantly private without governmental involvement. Limited insurance schemes, often organised by employers, are available to some. However, most patients have to pay dentists directly. Some public services are available free to children and to treat dental emergencies. Some dental hygienists and other clinical auxiliaries are employed.

The models for the provision of oral health care in the Netherlands, Iceland and Ireland do not totally resemble any of the previously described models and can be described as Hybrid. All five models have their roots in the history, cultures and social aspirations of the countries concerned. It should be noted that recent health care reform in the Nordic and Bismarckian systems is resulting in a shift towards increased private funding for certain aspects of health care, including dental care, that were previously free.

The Position in Ireland

In Ireland there were 1,896 registered dentists and 172 registered hygienists in the year 2000. There are two dental schools located in Dublin and Cork, producing approximately 70 dentists and 20 hygienists annually. The Dental Council regulates dentists and hygienists working in Ireland. Hygienists may practise under the supervision of a dentist. Other types of personnel complementary to dentistry are under consideration by the Dental Council.

Public Funded Dentistry

The Department of Health and Children is responsible for planning oral health care. The system is administered through 11 regional health boards. Since 2000 all children under the age of 16 years who attend state primary schools have access to free dental care through the Health Board Dental Service.

Children aged 7, 9, 11 and 13 years are targeted for screening and for application of preventive measures, oral health education, fluoride mouth rinsing in non-fluoridated areas and fissure sealing of vulnerable permanent molar teeth. Children are also screened for orthodontic treatment, which is free of charge to children in severe categories of need. Practically all services for children are delivered by salaried dentists (309) and dental hygienists (37) in the community service, and by over 40 dentists, including 9 consultants in the hospital service.

The health board dental service also has responsibility for promoting oral health and for community preventive programmes including water fluoridation. The Dental Health Foundation plays a leading role in developing oral health promotion programmes.

Monitoring of oral health status in the population and other oral health services research is carried out by health boards in collaboration with University College Cork and Trinity College Dublin.

Children and adults with special needs who require more frequent dental care receive care from a Health Board dental team consisting of dentist, dental nurse and dental hygienist. Those in need of more complex care are treated in specialised units in Dublin and Cork.

A range of dental services including specialist services are provided through the Dental Schools and Hospitals in Dublin and Cork.

Public Funded Dental Scheme for Medical Card Adults

In 1994, a new dental service was introduced under the Health Act for low-income adults over the age of 16 years. This is referred to as the Dental Treatment Services Scheme

(DTSS). Approximately 1 million people are covered by this scheme, which is delivered by approximately 1,140 dentists in the private sector on a fee per item basis. It is essentially a basic dental care scheme similar to the Dental Treatment Benefit Scheme (DTBS) with examination, diagnosis, scaling, polishing, fillings, extractions, root treatments, gum treatment and prosthetic treatment (false teeth) provided free of charge. The DTSS scheme was phased in over a number of years but is now available to all medical card holders including those over 70 years of age who were recently added to the scheme. Total expenditure on the DTSS in the year 2001 was €48 million.

Social Insurance Funded Dental Scheme

The Department of Social, Community and Family Affairs operate the Dental Treatment Benefit Scheme (DTBS). Over 1,200 private dentists provide a range of dental treatments to persons who contribute to Pay Related Social Insurance (PRSI); some treatments are provided free of charge while part of the cost of other treatments must be met by the patient. Spouses of those entitled to this care are also covered. The number of insured persons eligible for dental benefit is 900,000. In addition about 300,000 spouses are covered for dental benefit. It is estimated that 300,000 persons have 'dual eligibility' under the DTBS and the Dental Treatment Services Scheme (DTSS), which is described above. Expenditure on the DTSS in 2001 was €35.5 million.

Private Health Insurance

A limited number of dental procedures are covered by private health insurance. These relate mostly to in-patient oral surgery.

Private Practice

There is a very strong tradition of private practice dentistry in Ireland and a great reluctance to become involved in third party funded dentistry especially in the more expensive specialised aspects of care. This has changed gradually in the primary care area with the profession very heavily represented in both state schemes. With a predicted expansion in the delivery of publicly funded specialised dental care it will be interesting to see the approach adopted by private specialists to third party funded specialist dental care.

Future Needs

While many improvements have been made to the dental services since 1994 there still remain a number of weaknesses. In the children's dental service gaps in coverage persist in several areas, particularly in the border areas and on the western seaboard. Recruitment of salaried dental staff to these areas is problematic and there is also a scarcity of private

dentists in the same regions. Children under five are being identified as a special needs group requiring early intervention. Because they are not attending national schools they are not readily accessible. Dental services for other special need groups such as those with intellectual disabilities are in the early stages of development and will require considerable investment over the next ten years. A range of oral health promotion initiatives aimed at specific target groups need to be developed by the Dental Health Foundation, Ireland.

There are shortages of trained specialists leading to delays and waiting lists, especially in orthodontics. A framework is being put in place to establish publicly funded training programmes in a range of dental specialisations. A comprehensive evaluation of Dental Services currently underway and due for completion in 2002 should be used as a platform for planning a new dental strategy in 2003.

International Comparisons

Comparisons between health care systems on an international basis are difficult due to the differences in both finance and delivery of care. However, the number of dentists per head of population, spending on health, both general and oral, and some oral health outcomes may make some comparisons. The following table illustrates these points.

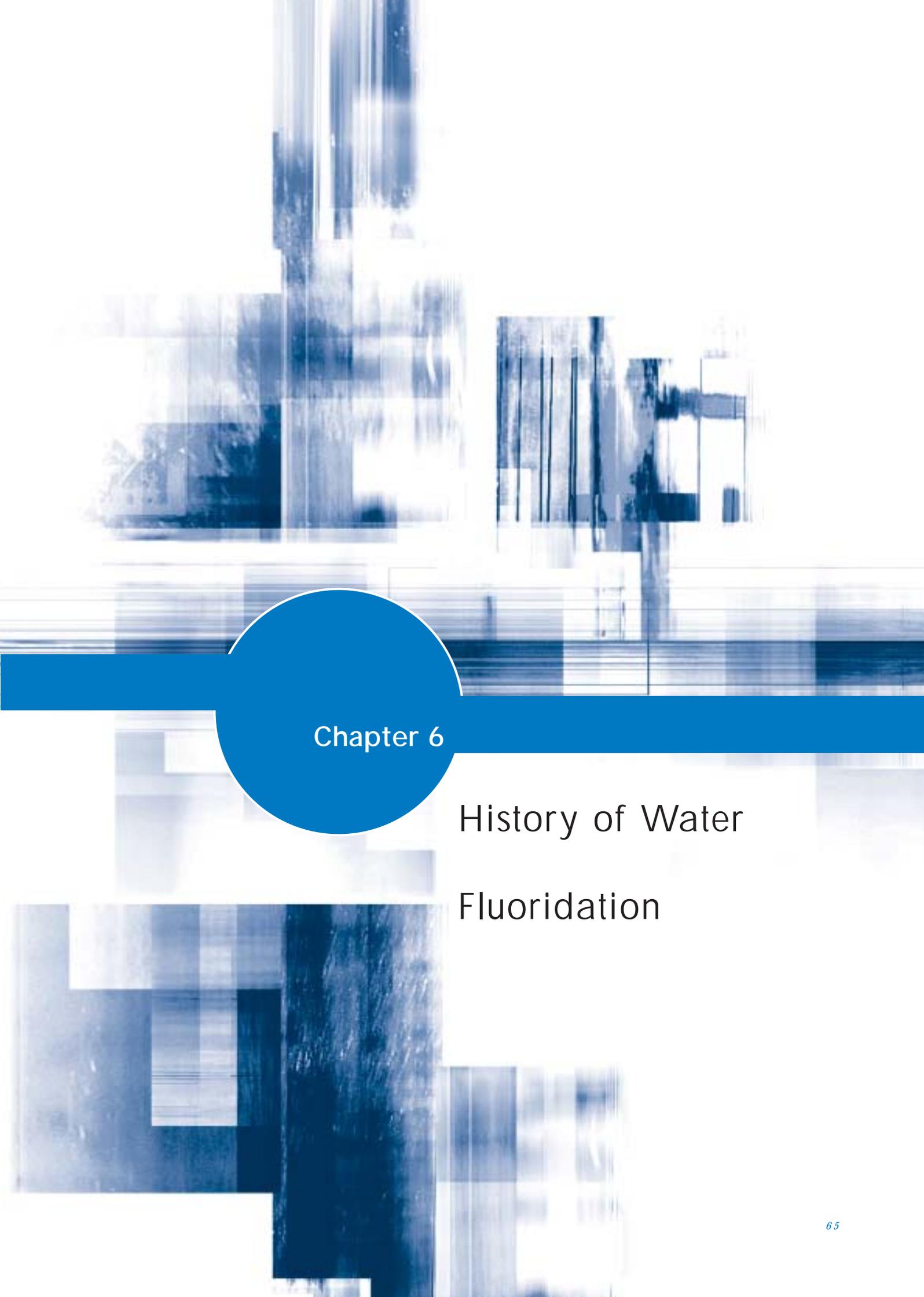
Table 5.1

Population; dental workforce; expenditure; oral health status

Country	National Population Data	Number of Active Dentists	Number of inhabitants per active dentist	Hygienists	%gdp spent on health	%gdp spent on oral health	DMFT at 12 years
Austria	8,030,000	3,122	2,572	0	8.3	0.46	1.70
Belgium	10,192,264	7,600	1,341	0	8.8	0.18	2.70
Denmark	5,294,860	5,139	1,030	857	6.5	0.56	1.01
Finland	5,150,000	4,852	1,061	1,171	7.3	0.44	1.10
France	60,832,449	40,451	1,503	0	9.7	0.50	1.94
Germany	82,100,000	62,024	1,324	100	10.4	0.90	1.70
Greece	10,500,000	12,609	833	0	8.5	0.40	2.70
Iceland	275,277	291	946	134	8.2	0.50	2.70
Ireland	3,860,000	1,770	2,181	172	6.8	0.25	1.10
Italy	57,226,000	44,642	1,282	600	6.8	0.39	2.12
Luxembourg	412,000	239	1,724	0	6.8	0.20	2.30
Netherlands	15,700,000	6,900	2,275	1,350	9.8	0.46	0.60
Norway	4,445,530	5,000	889	907	8.0	0.35	1.50
Portugal	9,957,300	1,850	5,382	118	8.2	0.35	3.08
Spain	39,674,000	14,877	2,667	1,000	7.4	0.50	2.30
Sweden	8,854,222	9,000	984	3,120	8.5	0.40	1.00
United Kingdom	59,008,634	26,051	2,265	3,833	5.8	0.29	1.40

Source: CECDO STAT, 1998

gdp = gross domestic product



Chapter 6

History of Water Fluoridation

History of Water Fluoridation

The International Context

In 1901, J.M. Eager, an American physician working in a United States Marine Hospital in Naples, Italy, described the condition now known as 'endemic dental fluorosis'.³³ He reported a high frequency of enamel defects and stained teeth among the inhabitants of towns near Naples. Local people called the condition 'Chiaie' and dentists thought that it was associated with the contamination of drinking water in the neighbourhood by volcanic debris from Mount Vesuvius. Following a change in the water supply to one town in the area, the incidence of this condition in children born subsequently was significantly reduced.³⁴

In 1902, Dr Frederick S. McKay, a dentist working in Colorado Springs, noticed that many of his patients' teeth were stained brown.³⁵ The condition was described locally as 'Colorado brown stain' and was called 'mottled enamel' by McKay. He noted an association with a deep-well water supply, and also that this mottled condition did not seem to increase the susceptibility of the teeth to decay.

McKay advised the citizens of Oakley, Idaho, in 1925 to change their water supply from a deep artesian well to a shallow well (Carpenter Spring). He observed that there was no fluorosis in the new permanent teeth.³⁶

Dr F.L. Robertson, a dentist in Bauxite, Arkansas, noted the presence of mottled enamel among children after a deep well was dug in 1909 to provide a local water supply. A theory that something in the water was responsible for mottled enamel led local officials to abandon the well in 1927.

In 1930, H.V. Churchill, a chemist with Alumina Corporation of America (ALCOA), an aluminium manufacturing company, when investigating the possible causes of mottled enamel in that area, used a newly available method of spectrographic analysis that identified relatively high concentrations of fluoride (13.7 parts per million) in the water of an abandoned well.³⁷ He informed McKay of this finding and arranged to have samples of water from other endemic areas analysed. He found the following concentrations of fluoride:

Colorado Springs	2 parts per million
Oakley, Idaho	6 parts per million
Kidder, South Dakota	12 parts per million
Lidgerwood, North Dakota	11 parts per million

Similar observations were made in other countries. In the United Kingdom in 1933, Norman

Ainsworth observed that children living in Maldon, Essex, had less decay than children living elsewhere.³⁸

The identification of a possible causative agent for mottled enamel led to the establishment in 1931 of the Dental Hygiene Unit at the US National Institute of Health, headed by Dr H. Trendley Dean. Dean's primary responsibility was to investigate the association between fluoride and mottled enamel. He and his colleagues undertook major surveys and investigations to identify and describe the geographic distribution of endemic dental fluorosis.

Dean developed a standard of classification of fluorosis in order to record quantitatively the severity of mottling.³⁹ This classification is known as (Dean's) Index of Fluorosis and is a standard tool in epidemiology (study of disease patterns). It identifies six ascending levels of increasing fluorosis, ranging from zero (no fluorosis) to five (severe fluorosis). Photographs of dental fluorosis may be seen in chapter 12.

Dean noted that 'from the continuous use of water containing 1 part per million of fluoride, it is possible that the very mildest form of mottled enamel may develop in about 10 per cent of the group. In waters containing 1.7 or 1.8 parts per million, the incidence may be expected to rise to 40 per cent or 50 per cent, although the severity would be largely of the "very mild" and "mild" types.'⁴⁰

In 1942, Dean demonstrated that where drinking water supplies had a natural fluoride content of 1 part per million the prevalence of dental decay among children was well below average, yet the children did not have the mottled enamel which occurred when the level was in excess of 2 parts per million. He documented the prevalence of dental fluorosis for much of the United States.

The theory that dental decay could be prevented by adjusting the fluoride level of community water supplies from negligible levels to 1.0–1.2 parts per million was tested in a survey which showed that the decay experience was twice as high in a low fluoride area as compared to a high fluoride area (50 per cent greater).

This was followed by extensive epidemiological surveys of dental decay prevalence and dental fluorosis for the United States Public Health Service during the late 1930s. Dean and his co-workers examined 7,257 children aged 12 to 14 years in 21 cities of four different states with a naturally high or low fluoride content in the public water supply. He showed that there was a clear inverse relationship between decay prevalence and fluoride content of the drinking water - the higher the fluoride content the lower the prevalence of dental decay. He also noted that there was a direct relationship between the dental fluorosis index (DFI) and the concentration of fluoride in the drinking water.

Following these investigations the United States Public Health Service decided to adjust the fluoride level of the water supplies to obtain a concentration of 1 part per million. Artificial fluoridation of domestic water supplies was first introduced in Grand Rapids, Michigan in January 1945, with Muskegon acting as the control city. The purpose of a control is to establish what would have happened if no artificial adjustment was made.

Several studies followed, which demonstrated that the addition of fluoride to bring the concentration in drinking water to 1 part per million reduced the incidence of dental decay by approximately 50 per cent. Major fluoridation studies, also begun in 1945, were in Newburg (fluoridated) and Kingston (control) in New York State, Evanston (fluoridated) and Oak Park (control) in Illinois and, outside the US, in Brantford (fluoridated) and Sarnia (control), both in Ontario, Canada. Subsequently, studies were initiated in several different countries outside North America. All these studies, which were carried out by different investigators in different countries and locations, consistently reported reductions of dental decay of much the same order of magnitude (i.e. over 50 per cent).⁴¹⁻⁴⁸ The prevalence of dental fluorosis in the communities where fluoride content was artificially raised was also comparable with what had been observed in cities where drinking water contained natural fluoride at about 1.0 part per million.

The effectiveness of community water fluoridation in preventing dental decay prompted rapid adoption of this public health measure in cities throughout the US. As a result, dental decay declined dramatically during the second half of the twentieth century.

The American Medical Association, the World Health Organisation, and other professional and scientific organisations quickly endorsed water fluoridation. Knowledge about the benefits of water fluoridation and its mode of action led to the development of other methods for delivery of fluoride, such as toothpastes, gels, mouth rinses, tablets and drops.

Since the early days of community water fluoridation, the prevalence of dental decay has declined both in communities with and communities without fluoridated water in the United States. This trend has been attributed largely to the diffusion of fluoridated water to areas without fluoridated water through bottling and processing of foods and beverages in areas with fluoridated water and widespread use of fluoride toothpaste.⁴⁹ The same phenomenon, which is known as the halo effect, has occurred in Ireland.¹⁷

The British Government sent a mission to the United States and Canada in 1952. It reported back to the UK Government and suggested that demonstration studies be carried out. These studies commenced in 1955 in Kilmarnock, in Anglesey and in Watford. They did not all run for the same period of time; Kilmarnock dropped out early. When these investigations were completed, the findings were in accordance with those of the American studies.

The Irish Context

An historical analysis of Ireland's mandatory fluoridation policy was undertaken by Dr Paul Beirne in 1999 and was presented in a thesis for a Master's Degree in Dental Public Health in University College Cork.⁵⁰ Much of the following information has been taken from that source.

In 1944, the problem of dental decay had been engaging the attention of Dr Conn Ward, Parliamentary Secretary to the Minister for Local Government and Public Health, Mr Seán

McEntee, and he advised that the National Nutrition Survey be expanded to include investigation of this problem.⁵¹ It was thought that nutrition and diet had a bearing on dental decay incidence and prevalence.

This survey, which began in 1946, provided the basis for a subsequent study of dental health of Irish children. At that time an inverse relationship had been observed between dental decay experience and dietary intake by Channel Island children during the occupation of the Second World War – the poorer the nutrition the higher the incidence of decay.

In July 1951, the Minister for Health, Dr James Ryan, appointed The Dental Consultative Council to advise the Minister on 'the improvement and extension of the dental services at present provided by the local authorities'. The Council presented its report in 1953 and recommended that four groups should be provided with dental treatment on a priority basis:

- Pupils of national schools
- Children attending child welfare clinics and expectant and nursing mothers
- Adolescents (14 to 19 years)
- Adults eligible for treatment under the Public Assistance Act.

At this time the dentist to population ratio in Ireland was 1 per 5,300 of the population, which compared unfavourably with other countries such as Norway (1: 1,600), Sweden (1: 2,300), Denmark (1: 2,300), Scotland (1: 4,100) and England and Wales (1: 4,600).

The Council advised that local authorities should estimate their dental requirements for schoolchildren on the basis of 1 dentist to 3,000 children, and the requirements for pre-schoolchildren, adolescents and adults on the basis of 1 dentist to 4,000 persons. Using these ratios it was estimated that 325 dentists would be required in the local authority dental services to cater for the four priority groups they had identified. The Council's recommendations were not based on any assessment of the size of the problem of dental decay in Ireland.

In 1952, the Minister for Health requested the Medical Research Council (MRC) to carry out a survey 'to ascertain whether there were significant differences in dental conditions amongst schoolchildren living in different areas of the country, and whether such differences, if they existed, could be related to differences in the dietary intake of children'.⁵²

The MRC responded by organising an epidemiological survey which showed that dental decay experience among schoolchildren was high in all the survey areas, and that the prevalence and severity of the condition was independent of the environmental or domestic circumstances and dietary habits of the children.

Of those examined in the 5-6, 7-8 and 12-13 year age groups only 4.3 per cent, 1.4 per cent and 1 per cent, respectively had complete sets of teeth (dentitions) free from decay.

The average number of decayed, missing and filled teeth (DMFT) per child aged 7-8 years was 6.9 (i.e. almost 7 teeth per child).

All of these results indicated that the recommendation of the Dental Consultative Council that 325 dentists would be required in the local authority dental services to cater for priority groups was totally inadequate and in the prevailing economic circumstances was unrealistic.

In 1957, the local authorities employed 73 whole-time dentists; in 1964 this figure had risen only to 93, which included 8 senior dental officers who were involved in supervisory and administrative duties. There were also limited numbers of newly qualified dentists. In 1953 the combined number of dental graduates from all the dental schools was 53, the majority of whom emigrated as soon as they qualified.

Failure to increase the numbers of dentists employed by the local authorities resulted in the Department of Health changing its policy towards giving treatment priority to children to the relative neglect of adults. In May 1956 local authorities were informed that 'the Minister considers that where services are not sufficiently developed to provide full dental care for all persons entitled to such care, health authorities should concentrate on the making available of an adequate service for children in preference to other eligible groups'.

In the Dental Consultative Council's report, it was recommended that a wholetime dental surgeon should be appointed to the Department of Health 'in order that the Minister may be adequately advised on dental matters and in particular on those relating to local authority dental services'.

Séamus MacNeill was appointed as the Department's first full time Dental Advisor in 1953, and his appointment marked a turning point in departmental policy towards tackling the problem of dental decay.

In a report he outlined his proposals, marking the beginning of public health dentistry in Ireland:

The prevalence of dental diseases, the problems involved and the costs of adequately controlling them appears on the face of it almost insurmountable in view of our limited resources. At the present time we are trying to move from the position where the only resort is to the mass extraction of diseased teeth due to a general state of neglect. The resort to such measures is not only incompatible with the function of public health but cannot be indefinitely tolerated by an enlightened administration.

He listed the dental problems facing the health authorities as prevention or prophylaxis, conservation or control of dental decay, and emergency and radical treatments. Preventive measures, he believed, had previously been overlooked by both health authorities and dentists 'because the resulting benefit did not show up immediately in records of work done in any given periods'.

MacNeill had raised awareness in the Department of Health of the public health benefits

that might accrue by fluoridating the public water supplies. The Assistant Secretary of the Department of Health, Paddy Murray, formally initiated the process of investigation of the benefits of water fluoridation. He was prompted by the findings of the United Kingdom Mission's Report on the Fluoridation of Water Supplies in North America, and requested a departmental review of the literature on water fluoridation.

Following a 14-month process of internal review, a general consensus developed as to the effectiveness and safety of fluoridation, a decision was taken by the Minister for Health, T.F. O'Higgins, to establish a Fluorine Consultative Council in 1957.

Its terms of reference were to advise the Minister for Health:

Whether with a view to reducing the incidence of dental decay it is desirable to provide for an increased intake of fluorine, and, if the Council considers it so desirable, to advise as to the best method of securing such an increased intake and any safeguards and precautions necessary.

In May 1958, the Council unanimously advised that:

Having considered all the information available to it on the relationship between fluorine and dental decay the Council is satisfied that an increased intake of fluorine will reduce the incidence of dental decay and that it is desirable to provide for such an increased intake. The Council is further satisfied that the increased intake of fluorine can best be provided by the fluoridation of public water supplies to the level of 1.0 part per million. In so recommending the Council is aware that not quite 50 per cent of the community would thereby benefit at present even if all public water supplies in the country were fluoridated, but the percentage will increase according as public water supplies are extended.

The Council had 'received representations to the effect that fluoridation of public water supplies was unethical, the main grounds of objection being that it was: mass medication, a usurpation of parental rights by public authorities, and an interference by the public authority with the integrity of the human body. These objections were carefully considered and advice was sought and received. The Council is satisfied that there is no ethical objection to the fluoridation of public water supplies within the margin of safety recommended in this report'.⁵³

At the time the Council reported its findings, it was not clear who had provided ethical advice. It was revealed subsequently at the time of the High Court challenge in 1963 (see Constitutional Challenge to Water Fluoridation below) that advice was sought from the Ethical Committee of the Guild of Saints Luke, Cosmas and Damien. This committee had been established with the approval of Archbishop McQuaid to provide advice for Catholic doctors on moral issues and dilemmas arising from their practice of medicine relating to such issues as sex education, contraception, abortion and the confidentiality of medical records. The finding of this committee was that 'fluoridation was ethically unassailable'.

In October 1958, the Government authorised the Minister for Health, Seán MacEntee, to lay the findings of the Consultative Council before each House of the Oireachtas and to issue simultaneously with the publication of the Report a statement that the Government had accepted in principle the recommendations contained in the Report and were considering what steps should be taken to give effect to them. Fluoridation of public water supplies was regarded as a much cheaper alternative than trying to increase the number of dental personnel in the country.

Prior to the introduction of water fluoridation, special legislation was required to legalise the addition of fluoride to the water, as under Irish law local (sanitary) authorities had the function to supply 'pure and wholesome water' to the public. Debate ensued as to whether this legislation should be enabling or mandatory.

Mandatory Legislation

The decision to make the legislation governing water fluoridation mandatory was considered the most satisfactory option by the Minister for Health. Such legislation 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.

Ensuing debate focused on the problems that would arise with enabling legislation:

- In many instances the boundaries of water supply areas overlapped; a decision by one local authority to fluoridate the water and by an adjacent authority not to fluoridate would result in major operational difficulties.
- It was believed by Department of Health officials that if the issue to fluoridate water was left to local authority members who would have to familiarise themselves with the results of a large body of scientific evidence, members who were unable to do so 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'.⁵¹

In December 1960, the Health (Fluoridation of Water Supplies Act) was promulgated as law (see Appendix 7).

This Act was to 'provide for the making by Health Authorities of arrangements for the fluoridation of water supplied to the public by sanitary authorities through pipes and to provide for certain other matters connected with the matter aforesaid'.

The Minister may make regulations as to the amount of fluorine (which shall not exceed one part by weight of fluorine per million parts of water) which may be added to a water supply.

Before any water supplies could be fluoridated, however, it was necessary under the Act that 'a survey of dental decay in a representative sample of pupils attending full-time day schools in the functional area or functional areas of the health authority or health authorities to whom the regulations relate' be carried out and also

an analysis or series of analyses of the quantities of fluorine and such other constituents as the Minister may determine in the water supplied by the sanitary authorities through pipes to the public in the functional area or functional areas of the health authority or health authorities to whom the regulations relate.

Section 6 of the Act stated that:

It shall be the duty of the Minister to arrange from time to time for such surveys as appear to him to be desirable to be made as respects the health, or any particular aspects of the health, of persons, or of particular classes of persons, in the functional area of a health authority in relation to whom regulations under the Act are in force.

The dental decay surveys were undertaken by the Medical Research Council at the request of the Minister for Health. A team of public health dentists with their recording assistants carried out the survey examinations. The surveys began in May 1961 and ended in December 1963, when the entire state had been covered. In all over 96,000 children were examined. The surveys disclosed high levels of decay in all areas. Although there were variations from place to place, the overall results showed uniformly poor dental health.⁵⁴ The methods and criteria for this series of surveys were a duplication of those used in the 1952 survey. They did not take account of the early stages of the process of decay. Consequently the results have been accepted as an under-evaluation of the real levels of decay.

Every public piped water supply in the State was analysed and only five out of more than 660 supplies were found to contain any significant concentrations of fluoride.⁵⁵

Subsequent regulations made under the Act were concerned with the fluoridation of water supplies in individual local authority areas, and dealt with:

- The provision, installation and maintenance of equipment for fluoridation
- The making of arrangements for the addition of fluorine to the water
- The testing of the fluorine content of the water to which the fluorine has been added.

With regard to testing, the fluorine content '*shall be determined daily by a colorimetric method and in addition, shall be determined by a distillation method at intervals not exceeding two weeks during the period of six months after the date on which fluorine shall have been first so added and thereafter at intervals not exceeding four weeks*'.

A Constitutional Challenge to Water Fluoridation

Background

The 1937 Constitution stated some general social principles about the family as an institution and gave rights which were thought to be necessary for its protection. It also gave constitutional force to the personal rights of each citizen and contained a guarantee by the State to defend and vindicate those rights.

Written constitutions are of little importance if they can be overridden or amended by parliament and so the Constitution of 1937 provided that the National Parliament was not to pass any law which was repugnant to any of its clauses. If it did, the statute was, to that extent, invalid. The High Court was given jurisdiction to decide whether a law was invalid on this ground and an appeal from its decision could be brought to the Supreme Court. Thus, any legislation which was seen to take away or seriously interfere with rights given by the Constitution could be challenged in the High Court.

This was the context in which the legal challenge to the compulsory fluoridation of the public supply of drinking water was fought. The issues in the action were dictated by the meaning of the provisions of the Constitution. It decided fundamental issues on the meaning and extent of the guarantee by the State to defend and vindicate personal rights.

The constitutionality of the Act was challenged in the High Court in 1963 and in the Supreme Court, on appeal, in 1964. In July 1964, the decision of the Supreme Court was delivered and supported the constitutionality of the Fluoridation Act.

The Legal Challenge

When it was decided to fluoridate water in areas supplied by the Dublin water authorities, legal proceedings were taken by a Dublin woman, Mrs Gladys Ryan, alleging that the Health (Fluoridation of Water Supplies) Act, 1960 if implemented would result in an infringement of personal and family rights and would be unconstitutional.

The first argument contended that the Act of 1960 was invalid because:

- It was a violation of the inalienable and imprescriptible rights guaranteed to the Family by Article 41 of the Constitution, by which the State guarantees to protect the family as an institution. (Inalienable means that which cannot be transferred or given away, while imprescriptible means that which cannot be lost by the passage of time or abandoned by non-exercise.)

- It was a violation of the inalienable right and duty of parents to provide, according to their means, for the religious, moral, intellectual, physical and social education of their children given by Article 42 of the Constitution.
- It was a breach of the guarantee in Article 40 of the Constitution by the State 'in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen'.

Mrs Ryan put forward the case that the Act had not respected her right to bodily integrity, and that the fluoridation of the public water supplies was or might be dangerous to the health of all or some of the citizens, and that in passing the Act of 1960 the Oireachtas had failed to respect and as far as practicable, by its laws to defend and vindicate the right of the citizen to life and bodily integrity.

Mr Justice John Kenny, High Court judge, rejected the first argument because, when the Constitution was passed, there were many acts in force which regulated the quality and contents of food and drink and so, if fluoridation was beneficial, it could not be an infringement of parental authority. This decision was confirmed in the subsequent Supreme Court appeal, where five judges decided that there was nothing in the Constitution which recognised the right of a parent to refuse to allow the provision of measures for the good health of the child when those were not harmful.

On the issue of the right of parents to educate their children, Mrs Ryan argued that education included rearing and nurturing and that altering water in its natural state by adding fluoride was, therefore, an interference with this right. The Court decided that the education referred to in the Act was one of a scholastic type because there was a later reference to parents being free to provide this education in their homes or in schools.

With respect to the third argument, Mrs Ryan argued that the general guarantee by the State to respect the personal rights of the citizen had been infringed, because those included a right to bodily integrity which, it was said, was violated as the fluoridation of water involved a hazard to health.

Justice Kenny in his judgment stated that the Constitution specified some personal rights (personal liberty, equality before the law), and guaranteed liberty for the exercise of others (the right to assemble peaceably and without arms and to form associations and unions). He also stated that while the Constitution did not give an exhaustive list of the personal rights which have a constitutional guarantee, the citizen had rights which, though not mentioned, had this protection and that the right to bodily integrity was one of them.

It became necessary then to consider whether the addition of the fluoride to water involved a risk to health. Experts in the fields of chemistry, medicine, epidemiology and dentistry were invited to consider the pleas as to the harmful effects of fluoridation.

On hearing this expert evidence and having read the relevant literature, Justice Kenny concluded that 'the fluoridation of public water supplies in Ireland at a concentration of 1

part per million will not cause any damage or injury to the health of anybody, young, old, healthy or sick who is living in this country and that there is no risk or prospect whatever that it will'. Justice Kenny ruled that Mrs Ryan's rights were not infringed in any way and the action was dismissed.

The case was appealed to the Supreme Court in 1964. The Court again ruled in favour of the constitutionality of the Fluoridation Act.

The Implementation and Evaluation of Fluoridation in Ireland

After the court's final decision, the physical process of fluoridation went into operation. Within the remaining six months of 1964, more than 25 per cent of the population of the State were receiving water from fluoridated piped water supplies. This included the greater Dublin area and the adjacent areas on the east coast.⁵⁶

Over the following seven to eight years all the major urban communities were fluoridated. By 1976, 57 per cent of the population received piped fluoridated water in their homes and by the time of the publication of this Report 71 per cent of the total population (3.8 million) resided in fluoridated communities.

In 1969, following six years of water fluoridation in the Dublin area, a dental decay survey was performed using the methods employed in the 1961 baseline surveys. School children aged 4 to 16 years were examined. The decay experience in deciduous teeth was documented. Among boys there was a reduction of 72 per cent at age four, 66 per cent at age five and 54 per cent at age six. The corresponding reductions among girls were 77 per cent, 63 per cent and 53 per cent respectively. All these reductions were statistically highly significant. When the levels of decay in 1952 and 1961 were compared there was little difference noted and it was not until after the introduction of fluoridation that any appreciable difference was found.⁵⁵

Starting in the 1970s similar studies of dental decay were performed in Cork, four years after the commencement of water fluoridation.⁵⁷ As well as confirming the results of the other, similar studies, this study was notable for being among the first to show that children born before the advent of water fluoridation locally also benefited from the measure. This showed that teeth formed and even erupted into the mouth prior to the commencement of fluoridation received some, if not all of the benefit. Part at least of the reason for this was seen as the effect of ionic fluoride in the saliva. This finding was subsequently confirmed in other studies.

Studies in the late 1970s showed that the prevalence of dental decay in schoolchildren had declined, not only in lifetime residents of fluoridated communities, but also in those living in non-fluoridated communities, the decline being greater in the former group.⁵⁸ This

phenomenon is called the 'halo effect'. It is attributable to the presence of fluoride in common items of food and drink which are manufactured in the larger fluoridated towns and cities and thereafter distributed widely in surrounding non-fluoridated areas. The fluoride content of these items causes a reduction in dental decay experience which is noticeable even if not as great as in fluoridated areas.

In 1984 the Minister for Health commissioned a national survey of children's dental health, the main aim of which was to measure the effectiveness of water fluoridation in the prevention of dental decay.^{16,17} The percentage of 5-year-old children recorded as having no decay in their primary teeth increased from 15 per cent in 1961-1963 to 52 per cent in 1984 in lifetime residents of fluoridated communities. The percentage of children living in non-fluoridated communities, with no decay in their primary teeth also increased, reaching 38 per cent in 1984.

In 1961-1963, 34 per cent, 6 per cent and 2 per cent of 8-, 12- and 15-year-old children respectively were decay free. In 1984, in the fluoridated group, the percentages with no decay in these three age groups were 69 per cent, 23 per cent and 12 per cent respectively. In the non-fluoridated group the corresponding figures were 56 per cent, 15 per cent and 8 per cent.

Between 1961-1963 and 1984 a major decline in the average number of decayed, missing and filled teeth per child number occurred in all four age groups, the decline being greatest in those children who had lived all their lives in fluoridated communities. The average number of decayed, missing and filled teeth of 5-year-old residents of fluoridated communities in 1984 was 1.8 compared with 3.0 in the non-fluoridated group, a difference of 40 per cent.

In 1992, 1993 and 1995 further major studies of dental decay levels in children were conducted in the Western, Eastern and North Eastern health board areas. It should be noted that as a result of the considerable expansion of the fluoridation programme in the former Eastern Health Board area, now the Eastern Region Health Authority, between 1984 and 1993, it was not possible to obtain a representative sample of lifetime residents of non-fluoridated communities in that area.

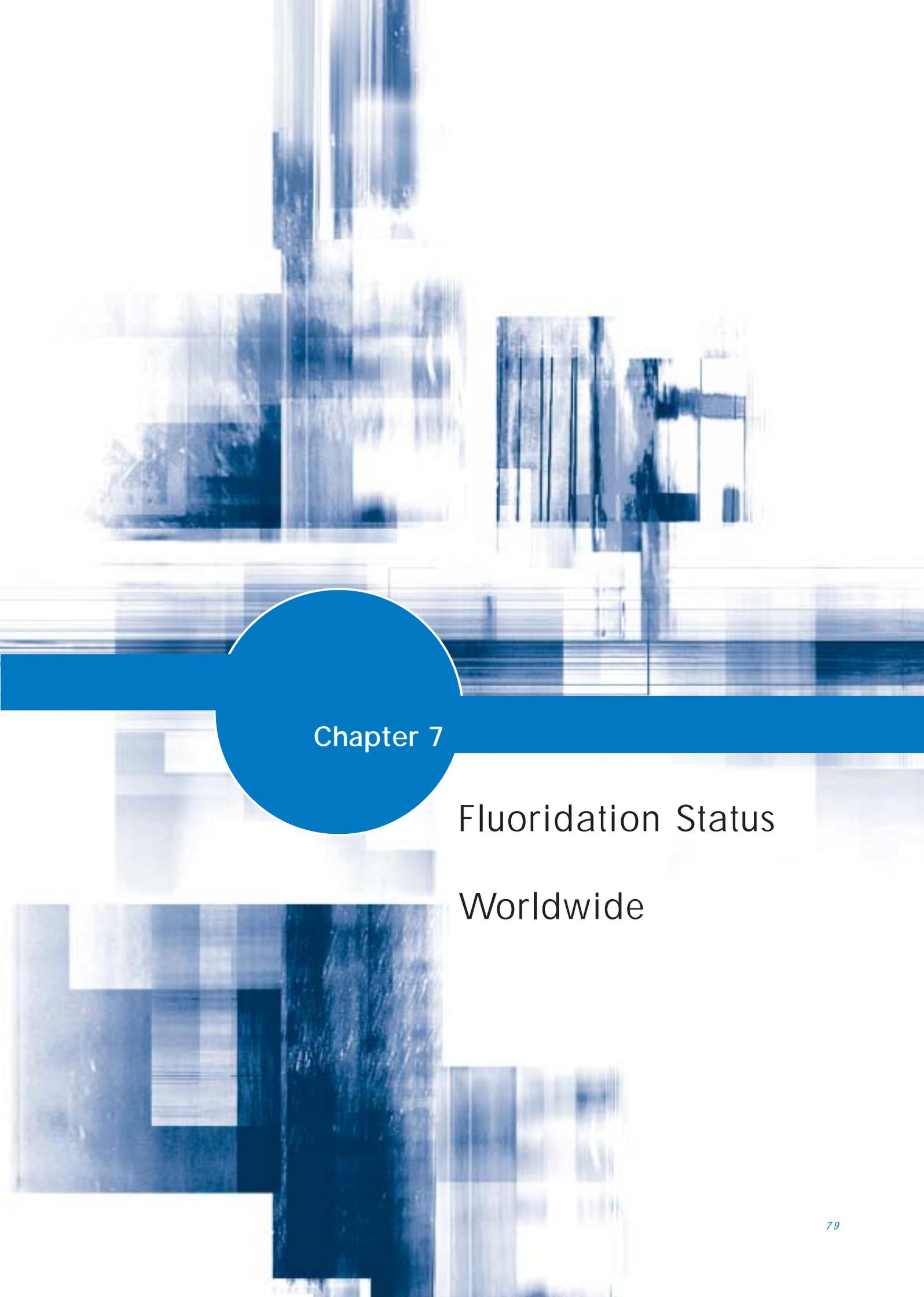
In the Western Health Board area, in 1992 the average number of decayed, missing and filled teeth of 5-year-old residents of fluoridated communities was 1.0 compared with 2.1 among the non-fluoridated group, a difference of 52 per cent. In the case of 12-year-olds, a difference of 27 per cent was observed.

In 1990-1991 a national survey was conducted to measure the effectiveness of water fluoridation among Irish adults.⁴ The outcome measures of oral health were: average number of decayed, missing and filled teeth, average number of teeth present per person, percentage with more than 20 natural teeth present, and percentage of people without any natural teeth. For all four outcome measures and for all age groups disease levels were lower and dental health was better in those who were residents of fluoridated communities.

Chapter 6 History of Water Fluoridation

The percentage of exposed root surfaces with decay was lower among those who resided in fluoridated communities. This result was achieved despite the fact that tooth loss is considerably higher in non-fluoridated communities.

The decline in the prevalence of toothlessness and the increase in the number of persons retaining their natural teeth into old age are likely to result in an increased risk of root surface decay.



Chapter 7

Fluoridation Status
Worldwide

Fluoridation Status Worldwide

Approximately 317 million people in 39 countries benefit from artificially fluoridated water. An additional 40 million benefit from water supplies which are naturally fluoridated. Community water fluoridation schemes have been in existence in the United States for over 50 years and are employed in 39 countries throughout the world including Spain, Switzerland, Australia, Canada, the United Kingdom, Israel, Singapore and New Zealand.

Legislation authorising the adjustment of water fluoride concentrations is of two types. It may be mandatory, requiring that a Ministry of Health or communities of a certain size fluoridate their public water supplies if they are deficient in fluorides. The legislation may be permissive or enabling, empowering the Ministry of Health or a local government to institute fluoridation. In a few countries, principally the United States and Canada, legislation of either the mandatory or enabling type may allow or require a popular vote.

The United States is now 65 per cent fluoridated and will soon reach the low 70s when California's water fluoridation law is implemented. In Australia approximately two thirds of the population reside in fluoridated areas, while in New Zealand 57 per cent of the population consume fluoridated water. The Japanese Government has recently endorsed water fluoridation as an appropriate means of reducing tooth decay rates. Vietnam commenced water fluoridation in the last 10 years. In South Korea, 39 cities are now fluoridated and 9 are in the process of installing fluoridation equipment.

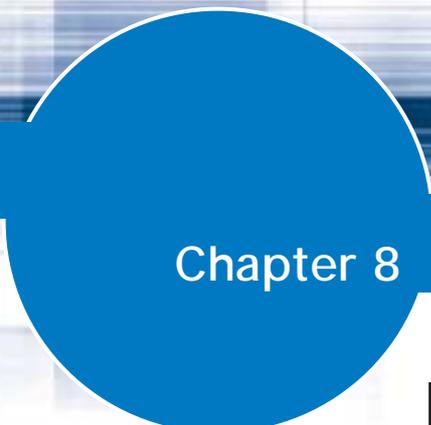
South Africa has enacted mandatory legislation requiring all water systems to fluoridate. Individual cities may request an exemption from the Health Department. This law will be implemented in about two years time. Brunei is preparing to commence fluoridation. Over 50 per cent of the water supplies in Israel are fluoridated. Implementation of regulations, which mandate water suppliers to fluoridate the water supply of every town with more than 5,000 residents will extend coverage to 90 per cent of the population. The deadline for the implementation has been postponed for one year (June 2002). This postponement was at the request of a number of water companies which had underestimated the time required to accomplish the fluoridation programme.

In Europe, the most common method for the distribution of fluoride to the population is through fluoridated salt. While roughly 13 million Europeans have access to fluoridated water, approximately 50 million EU citizens consume fluoridated salt. European countries which currently have fluoridated salt on the market, include Germany, France, Belgium, Austria, Switzerland and the Czech Republic. No country has banned the use of fluoride. Some countries have decided against water fluoridation for practical or political reasons. For example, in France there are over 20,000 separate public water sources, which makes water fluoridation technically difficult. Under these circumstances, other methods of delivery such as fluoridated salt, fluoridated milk, fluoride mouth-rinses and fluoride toothpaste have been employed to deliver fluoride to the population.

Several communities having initially started water fluoridation schemes have since ceased. The reasons to discontinue are usually complex. The Government in the Netherlands did not persist with water fluoridation because it was unable to supply fluoridated and non-fluoridated water to adjacent towns depending on the decision reached by communities sharing the same water supply. A body established by the Swedish government advised that water fluoridation should proceed. A bill was prepared but not enacted.

Methods of delivery of fluoride to populations at risk of dental decay have been discussed in Chapter 4.





Chapter 8

Public Water Supplies

Public Water Supplies

Background

Drinking water in Ireland originates from groundwater sources, surface water sources (including rivers and lakes) and springs.

Groundwater originates from under the earth's surface and quality depends on local circumstances, i.e. geology, agricultural practices, surface water influences etc.

Surface waters originate from a combination of sources such as rainfall on adjacent lands, direct rainfall to a river or lake, and groundwater contribution to the water body.

All waters will have their own unique characteristics depending on the actual source. Typical variations in raw water quality would be as follows:

- Peaty nature of upland waters
- Excessive iron and manganese levels of some ground waters
- Excessive hardness of waters of limestone origin

Levels of Treatment

Water for public consumption is required to meet the standards set out in European and National Legislation. The revised Drinking Water Directive (98/83/EC) was recently transposed into Irish law by European Communities (Drinking Water) Regulations, 2000 (S.I. 439 of 2000), and is effective from January 1, 2004.

Currently, Irish drinking water standards are fixed in Statutory Instrument S.I. No. 81 of 1988 - European Communities (Quality of Water Intended for Human Consumption) Regulations, 1988.

In order for these standards to be met various types/forms of treatment of the raw water have to be applied.

Statutory Instrument S.I. No. 294 of 1989, entitled European Communities (Quality of Surface Water Intended for the Abstraction of Drinking Water) Regulations 1989, sets out the following requirements and definitions of the standard methods of treatment for transforming of surface water of three categories of quality into drinking water (see Table 8.1).

Table 8.1
Transforming Surface Water into Drinking Water

Category	Standard of raw water	Level of treatment
A1	High quality (based on standards & monitoring regime)	Simple physical treatment and disinfection, e.g. rapid filtration and disinfection
A2	Progressively lower quality (based on standards & monitoring regime)	Normal physical treatment, chemical treatment, e.g. chlorination, coagulation, flocculation, decantation, filtration, disinfection (final chlorination)
A3	Progressively lower quality (based on standards & monitoring regime)	Intensive physical and chemical treatment, extended treatment and disinfection, e.g. chlorination to breakpoint, coagulation, flocculation, decantation, filtration, adsorption (activated carbon), disinfection (ozone, final chlorination)

Structure and Operation

A consumer can avail of water supplies as follows (see Table 2).

Table 8.2
Water Supply

Type	Service Provider	Source water provider	Approx. nos. households connected
Public water supply	Sanitary Authority	Sanitary Authority	950,000
Group water supply with public source	Group scheme	Sanitary Authority	90,000
Group water supply with private source	Group scheme	Group scheme	50,000
Private supply	Individual	Individual	120,000

The Environmental Protection Agency (EPA) publication *The Quality of Drinking Water in Ireland A Report for the year 1999 with a review of the Period 1997-1999* lists some 120 public water supply schemes, each supplying 5,000 or more consumers.⁵⁹ There are many more public water supply schemes that service less than 5,000 consumers. In addition, some 260,000 households approximately are connected to private and group water supply schemes.

The public water supply schemes are provided by public funds (Department of the Environment and Local Government, and Local Authority grants from various programmes) and are operated by the Sanitary Authority. A list of the principal fluoridated water supplies may be seen in Appendix 8.

The group water supply schemes and private schemes are provided by a combination of funds (DoELG grant and local funds) and are operated by the owners with the assistance of a state grant and subject to some procedural requirements.

Geographic Influences

The public water supply schemes generally cover areas with relatively dense populations where it is more economical to provide central water treatment systems. Some public water supply schemes have extended into more rural areas where this has been found to be technically necessary (due to a lack of other water resource options) or where it has been proved that extension of the larger scheme is more economical than a number of smaller schemes. Also, some schemes can have a number of raw water sources, each with different water treatment requirements.

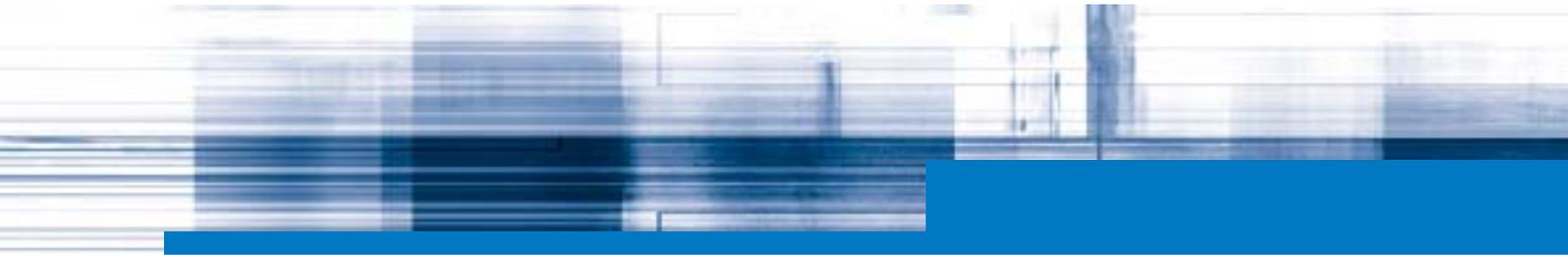
In many urban areas the expansion of the public water supply system will be driven by development and will be constructed as a consequence of technical considerations rather than with respect to local authority boundaries. As a consequence, it is common for one local authority to purchase water from a neighbouring authority and in some cases to re-export it to another local authority.

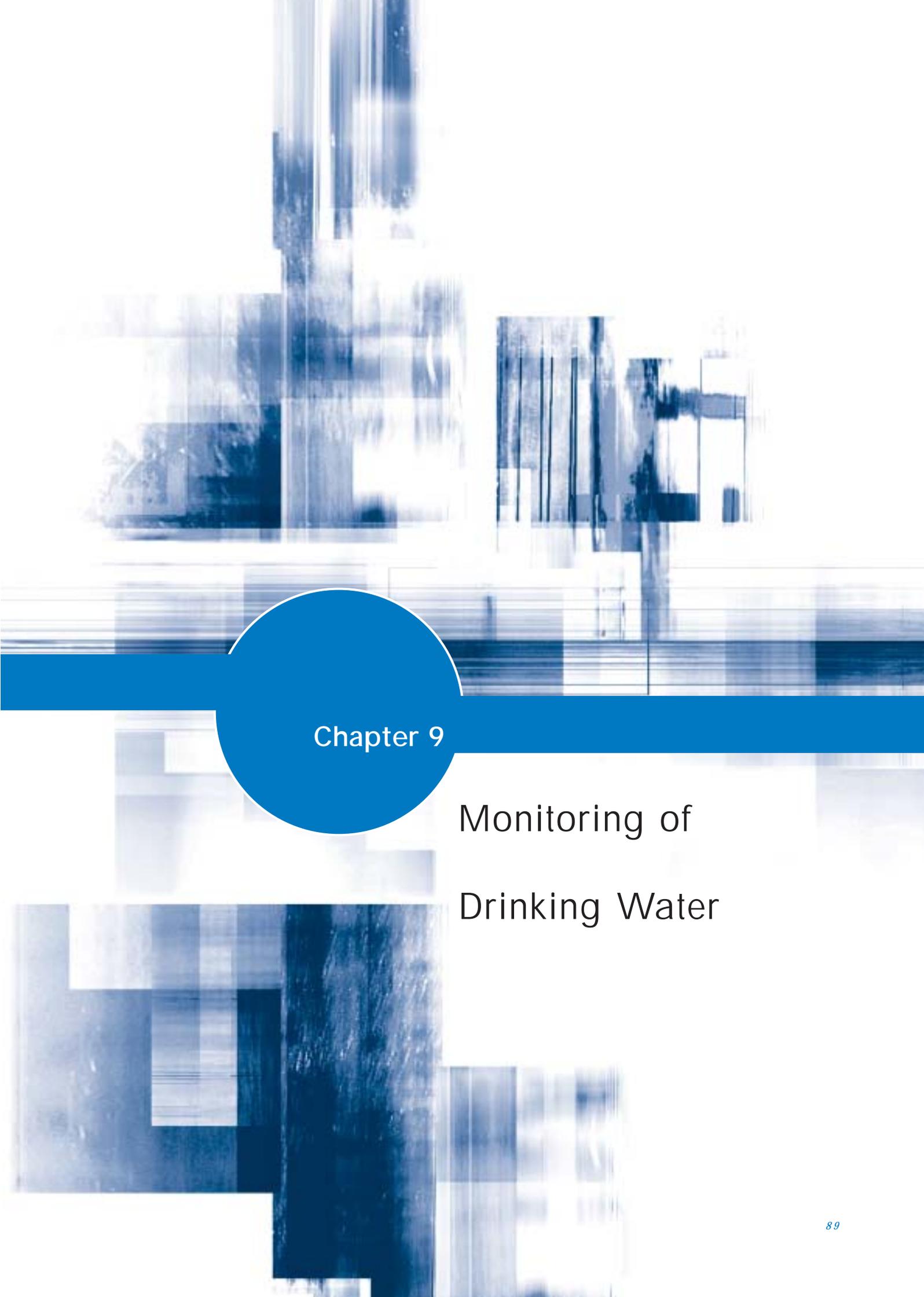
The distribution of water in the water supply network is a dynamic system and responds to daily variations in pressure, demand, and operational problems on an ongoing basis.

In the case of the Greater Dublin Area there are three main sources of water: Roundwood, Ballymore Eustace, and Leixlip. The treated water from these sources services consumers in Counties Wicklow and Kildare, and in the South Dublin, Fingal, Dun Laoghaire, and Dublin Corporation areas. While the blend of water being received by a particular customer will vary slightly on a daily basis (depending on local demand and operational practices) it could be significantly different at times of operational difficulty at a particular plant or during a drought period.

Conclusion

From a consideration of the above data it is clear that it would be technically impossible (if not incredibly expensive) to facilitate local authority implementation/non-implementation of fluoridation policy at a local level.





Chapter 9

Monitoring of Drinking Water

9 Monitoring of Drinking Water

Background

The European Communities (Quality of Water Intended for Human Consumption) Regulations, 1988 gave formal effect in Irish law to the original (1980) EU Drinking Water Directive (80/778/EEC). Under its provisions:

- All water for human consumption, whether in its original state or after treatment, regardless of origin, is covered, including water used in the food industry, but excluding natural mineral waters or medicinal waters.
- National quality standards, the legal limits, which must not be exceeded, are fixed for over 50 parameters.
- In particular circumstances, and only where there is no risk to public health, the Minister for the Environment and Local Government may grant 'departures' (exemptions) from the standard set for particular parameters.
- Minimum frequencies of sampling and analysis, for defined groups of parameters, are established by the Regulations. Samples are to be taken from water at the point where it is made available to the consumer, that is, at the consumer's tap.

Deficiencies in water quality confirmed by sampling and analysis are remedied according to procedures set down in the European Communities (Quality of Water Intended for Human Consumption) (Amendment) Regulations 2000.

The EU adopted a new Drinking Water Directive in November 1998 (Council Directive 98/83/EC). This is radically different from its predecessor and will entail changes in virtually all aspects of implementation – sample numbers, parameters, parameter classes, extent of coverage and so on. It was required that the administrative and legislative provisions necessary for the transposition of the new Directive into the legal framework of the EU member states be made by 25 December 2000 and, accordingly, new national Regulations were made in Ireland in late 2000. In accordance with the Directive, these Regulations specify that the full implementation of the new provisions shall be accomplished by 25 December, 2003. In practice the date of 1 January, 2004 will be used for implementation.

The new Directive was drawn up in order to adapt the previous Directive of 1980 to scientific and technological progress; experience gained from implementing that Directive showed that it was necessary to create an appropriately flexible and transparent legal framework for Member States to address failures to meet standards.

Monitoring for Fluoride

Under the fluoridation legislation monthly monitoring of fluoridated public water supplies is required to be carried out by the health authorities. This requirement for regular monitoring has been met from the outset, with sampling being carried out by authority personnel and analysis principally by the laboratories of the public analysts.

There is a second requirement for fluoride monitoring under the terms of the 1988 Drinking Water Regulations, whereby sanitary authorities must include fluoride in their analytical schedule. However, the extent of monitoring has been more variable than that just discussed, as the philosophy of the Drinking Water Directive (and hence the Regulations) is that the number of samples to be analysed rises in proportion to the size of supply, as indicated by the population served. For the smaller supplies as few as two or three samples a year may meet the requirement.

The situation has been compounded at times by the fact that some sanitary authorities delegate the implementation of the Drinking Water Regulations to the local health authorities, and the latter may provide the former simply with the results of the mandatory monthly monitoring, without taking further samples. However, the public may be assured that there is regular, ongoing and accurate monitoring of fluoride levels.

As the respective monitoring patterns of the 1980 and 1998 Drinking Water Directives, though very different, are complex in their structure a detailed discussion of them is inappropriate in the present context. However, it is important to note that there will be a markedly increased level of monitoring of drinking water when the Regulations made in 2000 come into effect.

Water Quality Standards for Fluoride

There is discussion of permissible fluoride levels in drinking water throughout this Report, but it is important to highlight the levels enshrined in EU legislation. It must also be explained that the Drinking Water Directives (as with other community legislation) are adopted only on the basis of meticulous consideration by the EU Commission and Council, by the European Parliament and by appropriate technical experts from the member states. Further, in framing proposals to be scrutinised thus, the Commission is guided by an expert group – the Scientific Committee on Toxicity and Ecotoxicity and the Environment – and takes full account of the current medical opinions of the World Health Organisation.

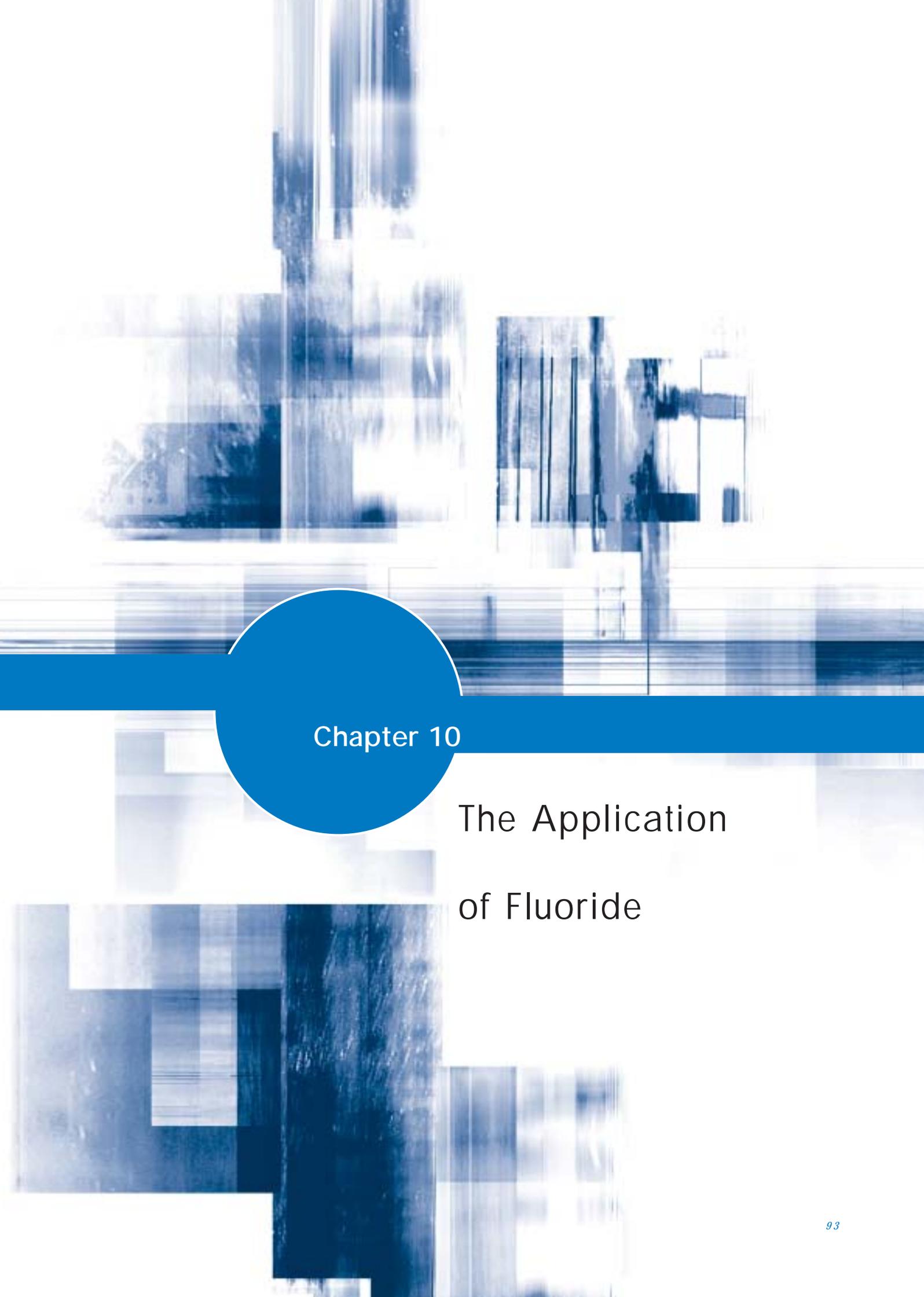
In the 1980 Directive the Community limit for fluoride in drinking water was specified as 1.5 mg/l (1,500 µg/l F). It is not without significance that in the 1998 Directive the same limit is specified, 1.5 mg/l F. However, in Ireland, the 1988 Regulations specified a limit of 1.0 mg/l F (1,000 µg/l F), in line with the upper limit in the national Fluoridation Act. This lower figure is still in force as the national standard.

The 1.5 mg/l F standard has been retained in the 1998 Drinking Water Directive, and the stricter standard of 1.0 mg/l F is specified in the 2000 Drinking Water Regulations. However, the latter contains the quality comment: 'the parametric value (i.e. the standard) is 1.0 mg / l for fluoridated supplies. In the case of supplies with naturally occurring fluoride the parametric value is 1.5 mg/l F'.

This provision does not imply a relaxation of policy or attitude towards drinking water quality standards; indeed such a position would contravene national and Community policy and the philosophy underlying the Regulations. It is a practical recognition of the fact that in some supplies, for which there are no alternative sources, natural levels of fluoride must be accepted up to the limit in the Directive. The provision of treatment to remove the relatively small increment (in chemical quantitation terms) of 0.5 mg/l F would be at best problematic and probably prohibitively expensive.

It has been explained that hydrofluorosilicic acid is added to drinking water in order to reduce the incidence of dental decay. The final concentration of hydrofluorosilicic acid in drinking water is required by legislation to 'not exceed 1 part by weight of fluoride per million parts of water' i.e. the limit just discussed. The limit in Ireland is two-thirds of that permissible elsewhere in the EU. (When individual Member States transpose the requirements of the Directive into their respective national laws, the relevant authorities may adopt quality standards which are stricter than those in the Directive, but may not adopt more lenient standards.)

The acid, at 14 per cent strength, with all its constituents, is diluted appropriately when it is added to water in the water treatment plants. As a result the concentrations of trace elements such as arsenic, lead, iron and so on are diluted by the same proportion. A draft EU standard (Pr En 12175 of 1998) for Hexafluorosilicic Acid for water treatment sets limits for eight toxic metals in the acid. These include such substances as antimony, arsenic, cadmium, chromium, lead, mercury, nickel and selenium. Details of the concentrations of these trace substances in the HFSA additive are given in Appendix 13.



Chapter 10

The Application
of Fluoride

10 The Application of Fluoride

Background Information

In Ireland public water supplies are fluoridated with hydrofluorosilicic acid (H_2SiF_6). Since 1990, the Eastern Health Board, now the Eastern Region Health Authority, has acted as agent for the nation's health boards for the purchase of hydrofluorosilicic acid.

When fluoridation commenced in the 1960s sodium fluoride was used for the first few years as the source of the fluoride ion. There were many problems associated with the use of a powder rather than a liquid.

The sodium fluoride powder was very hygroscopic (water-absorbent) and as water treatment plants are by their nature damp places there was a tendency for the powder to become solid, resulting in major difficulties in measuring accurate amounts to add to the water. The dust from the powder was a serious health and safety issue for water plant workers. The change to the liquid fluoride source occurred at a time when similar changes were taking place on a world wide basis.

The chemicals used for water fluoridation are manufactured to exacting quality standards. Within the EU drinking water whether fluoridated or non-fluoridated, is subject to the same stringent regulatory framework for water quality. The standards adopted in the Water Framework Directive 2000/60/EC including those for dangerous substances are consistent with the recommendations of SCTEE (EU Commission's Advisory Scientific Committee on Toxicity, Ecotoxicity and the Environment).

The fluoride chemicals come from the element fluorine. Fluorine, a gaseous halogen, is a natural component of the biosphere and the thirteenth most abundant element in the earth's crust. As such, it has been found in a wide range of concentrations in virtually all inanimate and living things. Fluorine is never found in a free state in nature, but is always in combination with other elements as fluoride compounds.⁶⁰

Fluoride is a negative ion and will combine with a positive ion to produce a generally very stable compound. The solubility of inorganic fluoride compounds varies widely. The solubility of calcium fluoride is 8 ppm, while the solubility of sodium fluoride is 18,000 ppm. If the water evaporates or is somehow reduced in volume, the ions may start combining again (precipitating) and fall out of solution.

When dissolved in water, these compounds break down (dissociate) into ions. It is the fluoride ions at the optimal level in drinking water which are responsible for dental decay reduction. Fluoride in water is present as the fluoride ion, regardless of the origin or natures of the additives used.

Owing to the universal presence of fluorides in the earth's crust, all water contains fluorides in varying concentrations. The bulk of the water available to humans is involved in the hydrological cycle, which means that it originates in the sea. Seawater itself contains significant quantities of fluoride at levels of 0.8-1.4 mg/l. In groundwater, fluoride concentrations vary with the type of rock through which the water flows and in Ireland levels are in the main significantly below 1.0 mg / l.

All foodstuffs contain at least traces of fluoride, as does all vegetation; it is absorbed from soil and water. Products in which skeletal tissue (bone) has been included during processing may have quite a high level of fluoride compared to those in which bone was removed. The highest levels in field-grown vegetables are found in curly kale (up to 40 mg/kg fresh weight) and endive (0.3-2.8 mg/kg fresh weight). Other foods containing high levels include fish (0.1-30 mg/kg) and tea.

Food processing influences the fluoride content of foods. The natural fluoride content of most foods is so small that its contribution is insignificant compared with the amount of fluoride produced through cooking and processing food in fluoridated water.⁶¹ High concentrations in tea can be caused by high natural concentrations in tea plants or by the use of additives during growth or fermentation. Levels in dry tea can be 3-300 mg/kg.

The Fluoridation Additive - HFSA

Fluorine occurs chiefly in fluorspar (CaF_2), cryolite and apatite. Fluorspar is a mineral containing between 30 to 98 per cent calcium fluoride. The hydrofluorosilicic acid used in Ireland is derived from fluorspar. It is produced in Spain by a company called *Derivados Del Flúor, S.A.* The acid is imported into Ireland by Albatros Fertilisers in New Ross, Co. Wexford, from where it is supplied, in a diluted form, to the water treatment plants throughout the country.

The hydrofluorosilicic acid (at a concentration of 37-42%) is transported to New Ross in a 4,000 gallon sealed rubber-lined container. On arrival, laboratory personnel from Albatros Chemicals analyse the acid to confirm the concentration and to determine the amount of water required for further dilution. The acid is then diluted to a concentration of $14.0 \pm 0.5\%$ H_2SiF_6 using water from the New Ross public water supply. The predetermined quantities of water and acid are put into a 2,000 gallon tank. Air is supplied for mixing and agitating.

After about five minutes the density is checked using a hydrometer. A reading of 1.118 denotes that the acid is within the tolerance of 13.5 to 14.5 per cent. A sample is taken to verify and certify the acid concentration. The diluted acid (14 per cent) is then stored in large storage tanks prior to distribution.

Quality Control

Independent analysis of the hydrofluorosilicic acid at all its concentrations is performed by Enterprise Ireland, on behalf of the Eastern Regional Health Authority. Samples are collected from storage tanks in New Ross (of both concentrated and diluted acid) and from the storage tanks in the water treatment plants. Samples are also analysed in the Public Analyst's Laboratory in Dublin. Levels of the following are determined: silicon, fluoride, zinc, lead, arsenic, chromium, cadmium, nickel, selenium, mercury, antimony and phosphorus.

HFSA at the Treatment Plant

Hydrofluorosilicic acid at a concentration of 14 per cent is delivered to water treatment plants throughout the country. Acid is stored in large, rubber-lined tanks in these plants, the capacity of which depend on the size of the individual plant. Acid is transferred on a daily basis to a 'day tank' which has a capacity for approximately a day's fluoride requirement. The tank is mounted on a scale and the weight before and after filling is recorded. From the day tank the acid is dosed directly into the water in proportion to the flow in the output main.

Dosage Rates

The HFSA is added to water in an amount which will result in a fluoride concentration in the treated water that will conform to the limits of 0.8 to 1.0 mg/litre as laid down in the legislation. The amount added may be calculated on either a weight or a volume basis. Dosing hydrofluorosilicic acid by volume is not as accurate as doing it on a weight basis because for a given concentration of acid the specific gravity can vary from one batch to another. Therefore dosing by weight is preferable where possible. However, the dilution required is so great that errors introduced by volume dosing will be quite small.

The actual concentration of hydrofluorosilicic acid is given on the laboratory report that comes with each consignment.

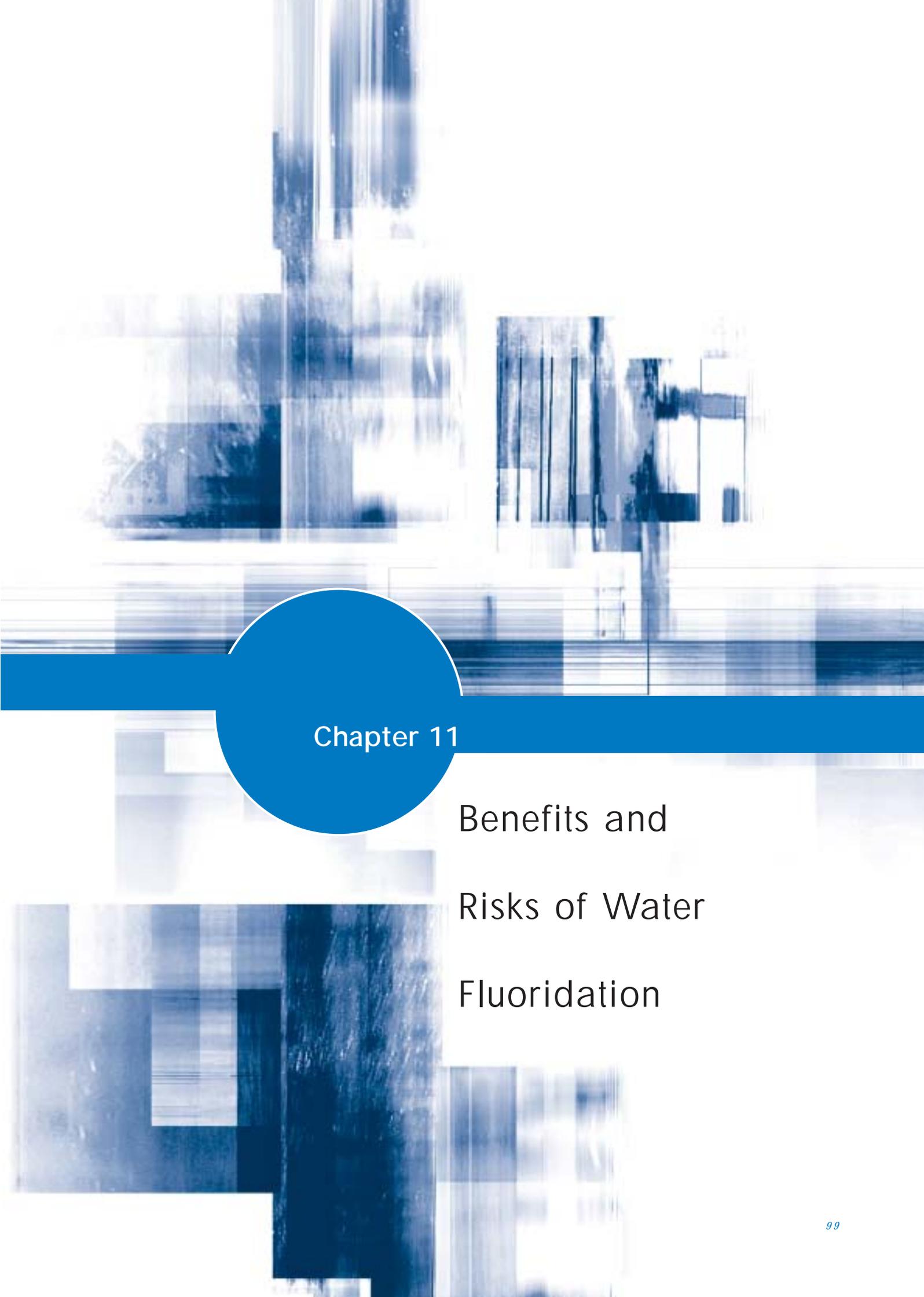
The following volume dosage rates will result in a fluoride concentration of one part per million by weight.

Table 10.1
Volume dosage rates to give 1ppmF.

Percentage hydrofluorosilicic acid	Kg acid per 1 million litres of water	Litres of acid per 1 million litres of water	Litres of water per kg acid	Litres of water per litre acid
13.5	9.36	8.357	106,800	119,658
13.6	9.30	8.304	107,600	120,430
13.7	9.23	8.241	108,400	121,343
13.8	9.16	8.179	109,200	122,271
13.9	9.10	8.125	110,000	123,007
14.0	9.03	8.063	110,700	124,031
14.1	8.97	8.009	111,500	124,861
14.2	8.90	7.946	112,300	125,843
14.3	8.84	7.893	113,100	126,697
14.4	8.78	7.839	113,900	127,563
14.5	8.72	7.786	114,700	128,440

Detailed additional information on HFSA, its manufacture, properties, quality control and metals content is presented in Appendices 11, 12 and 13.





Chapter 11

Benefits and Risks of Water Fluoridation

11 Benefits and Risks of Water Fluoridation

The benefit of water fluoridation is that it reduces the incidence of dental decay. Its use as a public health measure in the prevention of dental decay has been well documented over the past 60 years, and it has been widely accepted and recognised by public health authorities to be one of the most successful public health promotion measures introduced. Its safety and effectiveness have been endorsed by international bodies such as the World Health Organisation (WHO), the United States Public Health Service (USPHS), the Centre for Disease Control and Prevention (CDC) and the United States Surgeon General.

Dental Decay

There is a substantial body of literature comparing the prevalence and severity of dental decay among populations living in communities with differing levels of fluoride in the water supply. The initial research was conducted by Dean and his colleagues and culminated in the 'Twenty-One Cities Study' in the US. These studies showed that dental decay experience dropped sharply as fluoride levels rose to 1.0 ppm. This and subsequent research has been covered in Chapter 6. The 21 cities had varying levels of naturally occurring fluoride in the water supplies.

Although some of the early studies had a number of methodological limitations by today's standards, they showed that after 13 to 15 years of fluoridation, rates of dental decay in children living in communities that were fluoridated to 1.0-1.2 ppm were between 48 per cent and 70 per cent lower than in children living in control non-fluoridated communities. Since then, numerous studies have assessed the caries-preventive effect of water fluoridation. These studies have been the subject of a number of reviews, which confirmed the effectiveness of water fluoridation.⁶²⁻⁶⁶

Under Section 2 (4) (a) (1) of the Health (Fluoridation of Water Supplies) Act, 1960, surveys of the dental decay levels in each of the 26 counties in Ireland were conducted. In the period 1961 to 1963 these studies provided reliable and valid baseline information on decay levels in each county prior to water fluoridation. Fluoridation commenced in 1964 and over the next 8 years all the water supplies of the major urban communities in Ireland were fluoridated.

During the following 30 years the effectiveness of water fluoridation in the control of dental decay has been monitored on a regular basis through local and national surveys. All of these studies show that dental decay levels for children and teenagers were lower for those resident in fluoridated communities compared with those resident in non-fluoridated communities.^{4, 11, 16, 55, 57, 67-74}

A summary of some of these studies is presented in Tables 11.1, 11.2, and 11.3. In Table 11.1 it is seen that a total of 1,924 children aged 12 years were examined in the Western Health Board in the 1961-1963 baseline pre-fluoridation study. The average number of decayed, missing and filled teeth of these children (DMFT) was 4.2. In 1984, the corresponding average DMFT figures were 2.3 among lifetime residents of fluoridated communities compared with 3.0 among lifetime residents of non-fluoridated communities. This difference of 0.7 was equivalent to a difference of 23 per cent.

In 1992 a further study of 12-year-old children in the Western Health Board revealed the average DMFT among lifetime residents of fluoridated communities was 1.6 compared with 2.2 in lifetime residents of non-fluoridated communities, a difference of 32 per cent. Similar trends are apparent in the data presented in Tables 11.2 and 11.3 for the Eastern Health Board and the North Eastern Health Board respectively. These results show that in the period from the early 1960s to the mid-1990s, there has been a reduction in the level of dental decay amongst children in both fluoridated and non-fluoridated communities. The reduction however is greatest in fluoridated communities.

Table 11.1

Average number of decayed, missing or filled teeth (DMFT) in 5, 8 and 12 year old children in the Western Health Board in 1961-1963, 1984 and 1992

	1961-1963		1984				1992			
	Non-Fluoridated		Fluoridated		Non-Fluoridated		Fluoridated		Non-Fluoridated	
Age	n	DMFT	n	DMFT	n	DMFT	n	DMFT	n	DMFT
5	1,119	5.0	85	1.5	77	2.2	301	1.0	85	2.1
8	2,177	1.4	96	0.4	97	0.9	291	0.4	88	0.5
12	1,924	4.2	79	2.3	81	3.0	278	1.6	102	2.2

Table 11.2

Average number of decayed, missing or filled teeth (DMFT) in 8 and 12 year old children in the Eastern Health Board in 1961-1963, 1984 and 1993

	1961-1963		1984				1993	
	Non-Fluoridated		Fluoridated		Non-Fluoridated		Fluoridated	
Age	n	DMFT	n	DMFT	n	DMFT	n	DMFT
5	1,210	5.6	139	1.3	123	2.9	2,194	0.9
8	2,944	2.0	151	0.5	83	1.0	2,499	0.3
12	2,469	5.2	128	2.2	101	3.4	2,396	1.4

Table 11.3

Average number of decayed, missing or filled teeth (DMFT) in 5, 8 and 12 year old children in the North Eastern Health Board in 1961-1963, 1984 and 1995

	1961-1963		1984				1995			
	Non-Fluoridated		Fluoridated		Non-Fluoridated		Fluoridated		Non-Fluoridated	
Age	n	DMFT	n	DMFT	n	DMFT	n	DMFT	n	DMFT
5	1,293	5.0	89	1.0	139	2.1	263	1.2	307	1.8
8	2,604	1.5	90	0.5	125	0.6	289	0.4	312	0.5
12	2,401	4.3	89	2.3	132	2.8	321	1.3	351	1.6

The first national survey of adult dental health was conducted in Ireland in 1990.⁴ One of the main aims of this study was to measure the effect of water fluoridation on the oral health of adults. Using regression analysis to take account of confounding factors it was found that subjects who were resident in fluoridated communities for many years had better dental health than those who were resident in non-fluoridated communities. A summary of the findings of this survey is shown in Table 11.4.

Among those aged 25-34 years, the average DMFT in those resident in fluoridated communities was 14.7 compared with 16.9 in those resident in non-fluoridated communities. This latter group had on average 23 natural teeth compared to those resident in fluoridated communities who had 26 teeth of a potential total of 32.

Amongst those aged 35 to 44 years, who were resident for most of their lives in fluoridated communities, a total of 164 subjects were examined. The average number of natural teeth present amongst this group was 23, of a potential total of 32. Amongst the corresponding age group resident in non-fluoridated communities the average number of teeth present was 19 or 17 per cent.

Differences in disease levels and levels of oral health were equally striking in older age groups. For example, in those aged 55-64 years of age the percentage with more than 20 natural teeth remaining and the percentage with no natural teeth were 29 per cent and 34 per cent, respectively, in the fluoridated group compared with 9 per cent and 47 per cent respectively in the non-fluoridated group.

The percentage of exposed root surfaces with decay was lower among those who resided in fluoridated communities.⁷⁵

Table 11.4

Oral Health of Irish Adults 1989-1990

Age	Fluoridated					Non-Fluoridated				
	n	DMFT	Average no. natural teeth	% with > 20 natural teeth	% with no teeth	n	DMFT	Average no. natural teeth	% with > 20 natural teeth	% with no teeth
16-24	227	7.2	27.1	98.7	0.0	101	7.6	27.2	98.0	0.0
25-34	139	14.7	26.1	95.0	0.0	90	16.9	22.9	77.2	3.3
35-44	164	18.9	22.5	71.3	2.4	98	19.0	19.0	53.1	6.1
45-54	111	23.2	16.4	39.6	10.8	88	24.9	10.7	22.7	29.5
55-64	68	25.0	11.6	29.4	33.8	70	27.2	6.8	8.6	47.1
65+	78	26.5	9.2	16.4	42.3	107	27.9	5.9	7.5	54.2

As part of an adult dental health survey in Ireland in 1990, the general health of participating subjects was also assessed. General health was measured using the criteria developed by the American Society of Anaesthesiologists (ASA).

The ASA classifies a patient's condition before an operation as follows:

Class 1 = normal, healthy

Class 2 = mild systemic disease

Class 3 = severe systemic disease that limits activity but is not incapacitating

Class 4 = incapacitating systemic disease that is a constant threat to life

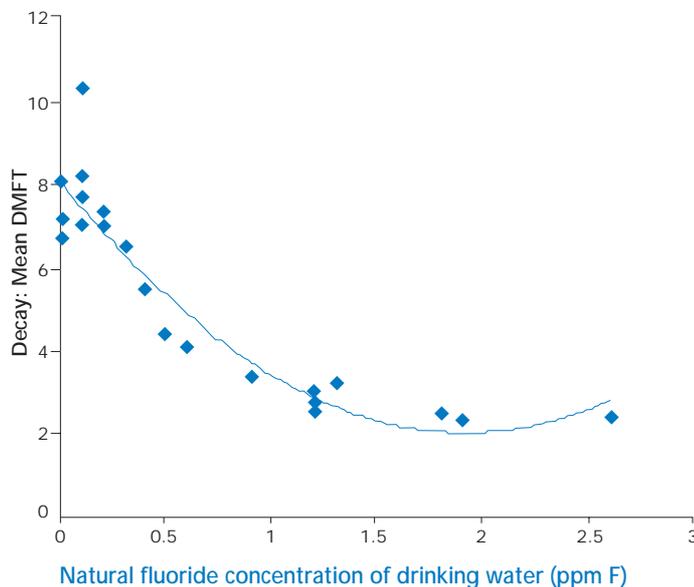
Class 5 = moribund and not expected to survive 24 hours with or without the operation.

The results of this part of the survey showed that there was no difference in the general health status of persons resident in fluoridated and non-fluoridated communities. For example, for those subjects aged 55 years and over the percentage in the ASA Class 1, 2, 3 and 4 were 65 per cent, 25 per cent, 10 per cent and 10 per cent respectively, in the fluoridated communities. The corresponding percentages in the non-fluoridated communities were 71 per cent, 19 per cent, 10 per cent and 10 per cent.

Mechanism of Action of Fluoride

The mode of action of fluoride in preventing and controlling dental decay has been clarified in recent years.⁷⁶ Researchers agree that the anti-caries effects of fluoride are almost exclusively, but not necessarily entirely, topical.⁷⁷ The possibility of a systemic effect on dental decay is less clear and is still being investigated. Maintaining a constant ambient level of fluoride in the oral cavity is essential for preventing or controlling dental decay.⁷⁶

Fluoride concentrated in plaque and saliva inhibits the demineralisation of sound enamel and enhances the remineralisation (i.e. the recovery) of demineralised enamel.⁷⁸ As cariogenic bacteria metabolise carbohydrates and produce acid, fluoride is released from dental plaque in response to lowered pH at the tooth-plaque interface. The released fluoride and the fluoride present in saliva are then taken up, along with calcium and phosphate, by demineralised enamel to establish an improved enamel crystal structure.¹⁰ This improved structure is more acid resistant and contains more fluoride and less carbonate. Cycles of demineralisation and remineralisation continue throughout the lifetime of the tooth.



Risks

The use of any health technology always necessitates an assessment of its relative benefits and risks. Fluoridation of drinking water is a health technology and as such necessitates a similar assessment. A description of risks will be given under the headings of dental health risks, i.e. dental fluorosis and general health risks.

Dental Fluorosis

Dental fluorosis has been defined as 'a dose response effect caused by fluoride ingestion during pre-eruptive development of teeth'. This change in the enamel is characterised by an altered appearance of the tooth ranging from fine white lines (which are difficult to see), to pitting or staining of enamel. Photographs of normal teeth and the various levels of dental fluorosis may be seen in Chapter 12.

Dental fluorosis may be viewed differently by the public and by the dental profession; the different perceptions may reflect individual circumstances as well as cultural values. Enamel mottling (dental fluorosis) was first recognised as a condition on the basis of the characteristic appearance of the teeth of children who had lived in certain areas.⁷⁹ The relationship with fluoride became known in 1931, and the term 'dental fluorosis' became accepted terminology in the mid-1930s. Following the identification of fluoride as a cause of mottled enamel, Dean developed a standard of classification of mottling in order to record quantitatively the severity of mottling. This classification is explained in Table 11.5 below.

The questionable and very mild categories have from the outset been recognised as a side-effect of water fluoridation and, more recently, have been recognised as a consequence of the use of other fluoridated dental and oral hygiene products, in particular fluoride toothpastes. For example, based upon the 21 cities study by Dean, water containing 1 ppm fluoride can result in approximately 50 per cent of the population having the questionable or very mild grades of fluorosis.

The 'very mild' form of enamel fluorosis described by Dean refers to 'small, opaque, paper white areas scattered irregularly over the tooth, but not involving as much as approximately 25 per cent of the tooth surface. Frequently included in this classification are teeth showing no more than about 1 to 2 mm of white opacity at the tip of the summit of the cusps of the bicuspid or second molars'.

The 'mild' is defined as follows: 'the opaque areas in the enamel of the teeth are more extensive, but do not involve as much as 50 per cent of the tooth surface'.

Table 11.5

Classification of Mottling

Classification	Criteria – Description of Enamel
Normal	Smooth, glossy, pale creamy-white translucent surface
Questionable	A few white flecks or white spots
Very mild	Small, opaque, paper-white areas covering less than 25 per cent of the tooth surface
Mild	Opaque white areas covering less than 50 per cent of the tooth surface
Moderate	All tooth surfaces affected; marked wear on biting surfaces; brown stain may be present
Severe	All tooth surfaces affected; discrete or confluent pitting; brown stain present

Although the predominant beneficial effect of fluoride occurs locally in the mouth, the adverse effect, dental fluorosis, occurs by the systemic route. Dental fluorosis is closely associated with fluoride intake during the period of tooth development.⁸⁰ Table 3.1 (in Chapter 3) shows the sequence of events in the developmental process of the primary teeth.

As the prevalence of dental decay has decreased some concern has been expressed that fluoride may be causing an increased amount of mottling of tooth enamel (dental fluorosis).

Fluorosis in Ireland

The prevalence of fluorosis in the Republic of Ireland has been monitored extensively using both local and national surveys. These studies have shown a slight increase in the prevalence of the questionable, very mild and mild grades of fluorosis. For example in the Eastern Health Board in 1984, 5 per cent of 8-year-old children had questionable fluorosis and 2 per cent had very mild fluorosis. In 1993 in the same age group, the presence of questionable fluorosis had increased to 19 per cent again 2 per cent had very mild fluorosis and 1 per cent had mild fluorosis. In 1997, in the Eastern Health Board in 12-year-old children the prevalence of questionable fluorosis was 14 per cent, very mild 6 per cent, mild 3 per cent and moderate 1 per cent.⁸¹ See tables 11.6 and 11.7. These data show that the prevalence and severity of dental fluorosis in Ireland is increasing. The levels of fluorosis, primarily of the milder forms, are cosmetic in nature and do not require treatment. Most changes are not visible to the untrained eye.

Table 11.6 Enamel Fluorosis Eastern Health Board		
Permanent Incisors		
	Dean's Index (%) 8 year olds	
	1984	1993
Questionable	5	19
Very Mild	2	2
Mild	0	1
Moderate	0	0

There is increasing evidence to suggest that fluorosis is due to the inappropriate consumption of fluoride toothpaste: children starting to use toothpaste too early and using excessive amounts, a significant amount of which may be swallowed.

Table 11.7 Enamel Fluorosis Eastern Health Board		
Permanent Incisors		
	Dean's Index (%) 12 year olds	
	1993	1997
Questionable	20	14
Very Mild	2	6
Mild	1	3
Moderate	0	1

Currently there is a national survey of children's dental health in progress in which measurement of dental fluorosis is a major component. This study includes not only clinical measurement but also photographic records of incisor teeth of large numbers of children in each health board in Ireland and in Northern Ireland. The results of this survey will give a clear indication of trends in the prevalence of dental fluorosis in Ireland.

A similar increase in the prevalence of dental fluorosis has also been reported in a number of other countries throughout the world. For example Kumar et al 1989 reported on the trends in dental fluorosis and dental decay prevalence in New York and found that there was an increase in the incidence of fluorosis over time. Similar findings had been reported in Canada.^{82, 83}

In the recent US Department of Health and Human Services report the increase in the prevalence of fluorosis in the US was referred to and on this basis it was recommended that strategies be adopted to reduce the intake of fluoride in infants and young children.¹⁰

General Health Effects

Background

The World Health Organisation has been instrumental in developing guidelines for drinking water quality. These guidelines are intended to be used as a basis for the development of national standards that, if properly implemented, will ensure the safety of drinking water supplies through the elimination, or reduction to a minimum concentration, of constituents of water that are known to be hazardous to health.

In developing guideline values, information is obtained from health effects resulting from exposure to chemicals.

Studies on human populations are one source of such information, but their value is often limited, due to the lack of quantitative information on the concentrations to which people are exposed or on simultaneous exposure to other agents.

The second information source, and the one most often used, is toxicity studies using laboratory animals. Such studies are limited due to the small number of animals used and the relatively high doses administered. There is a need to extrapolate the results to the low dose to which human populations are usually exposed.

In order to derive a guideline value to protect human health, it is necessary to select the most suitable experimental animal study on which to base the extrapolation.

Derivation of guideline values

For most kinds of toxicity, it is generally believed that there is a dose below which no adverse effects will occur. This is known as the NOAEL described below.⁸⁴

For chemicals that may give rise to toxic effects, a **tolerable daily intake (TDI)** is derived as follows:

$$\text{TDI} = \text{NOAEL or LOAEL} \div \text{UF}$$

Where NOAEL = no-observed-adverse-effect level
LOAEL = lowest-observed-adverse-effect level
UF = uncertainty factor

The **tolerable daily intake (TDI)** is an estimate of the amount of a substance in food or drinking water, expressed on a body weight basis (mg/kg or µg/kg of body weight), which can be ingested over a lifetime without appreciable health risk.

As TDIs are regarded as representing a tolerable intake for a lifetime, they are not so precise that they cannot be exceeded for short periods of time. The large uncertainty factors generally involved in establishing a TDI serve to provide assurance that exposure exceeding the TDI for short periods is unlikely to have any deleterious effects upon health.

The **no observed adverse effect level (NOAEL)** is defined as the highest dose or concentration of a chemical in a single study, found by experiment or observation, which causes no detectable adverse health effect. Whenever possible, the NOAEL is based on long-term studies, preferably of ingestion of drinking water. However, NOAELs obtained from short-term studies and studies using sources of exposure (e.g. food, air) may also be used.

The **guideline value (GV)** is then derived from the TDI as follows:

$$GV = TDI \times BW \times P \div C$$

Where BW = body weight (60 kg for adults, 10 kg for children and 5 kg for infants)

P = fraction of the TDI allocated to drinking water

C = daily drinking - water consumption (2 litres for adults, 1 litre for children and 0.75 litre for infants)

In summary, the NOAEL, which is derived from experimental situations or by observation, is divided by an uncertainty factor and when translated into what can be ingested over a lifetime without appreciable health risk, the tolerable daily intake (TDI) is calculated. The guideline value is then derived by taking account of the body weight, the fraction of the TDI allocated to drinking water and the daily consumption of water, which varies for adults, infants and older children.

Values for Fluoride

The major sources of fluoride intake are food, water, beverages and fluoride containing dental products. The atmosphere carries some fluoride, but it supplies only a small fraction of the daily exposure, except in heavily polluted areas.

Fluoride in water demonstrates what is known as the 'diffusion' or 'halo' effect. This is the result of the consumption of foods and beverages, manufactured in fluoridated areas, being consumed in non-fluoridated areas.

While it is not known if fluoride is essential for human health, it is well established that it decreases susceptibility to dental caries. Recommended intake values, expressed in milligrams per kilogram body weight are generally those amounts of fluoride that appear to

be beneficial in reducing or preventing caries, but do not cause toxic effects, in other words the tolerable daily intake and the NOAEL values as discussed above.

In the case of fluoride there is a NOAEL for two populations:

For children under 8 years of age (i.e. those at risk of developing dental fluorosis), it is accepted that the daily intake of fluoride which will not produce mild fluorosis in permanent teeth is 0.05 mg F/kg body weight/day, with a range of 0.02 to 0.1 mg F/kg/day. The LOAEL is 0.1mg F/kg/day. An intake slightly above this LOAEL for an extended period of time (several months or years) during tooth development is likely to produce dental fluorosis.

For children over 8 years and for adults (i.e. not at risk of dental fluorosis) a NOAEL of 10mg F/day is considered appropriate. In order to attain that level of exposure large amounts of water and toothpaste would need to be consumed over long periods.

In the 1940s an optimal dietary intake of fluoride by young children consuming fluoridated water was determined to be 0.05 mg F/kg body weight with a range of 0.04 to 0.07 mg/kg per day.^{85, 86} This intake provided a high degree of protection against dental caries and a low prevalence of dental fluorosis. This intake value is within the range of the NOAEL as quoted above.

In 1997, the Institute of Medicine in the United States published age-specific recommendations for total dietary intake of fluoride. These recommendations defined **an adequate intake** as 'intake that maximally reduces the occurrence of dental decay without causing unwanted side effects, including moderate enamel fluorosis' and a **tolerable upper intake** as 'the highest level of nutrient intake that is likely to pose no risks for adverse health effects in almost all persons'.

For children up to 8 years of age, an adequate intake of 0.05 mg F/kg/day was recommended, to prevent dental caries. This is the same value as the NOAEL, as quoted above.

A *tolerable upper intake* of 0.1 mg F/kg/day was recommended as a level unlikely to pose risk for moderate dental fluorosis. This is the same value as the LOAEL, as quoted above.

Fluoride Bio-availability

Bio-availability is the quality of a substance that renders it capable of interacting with and affecting biological processes.⁸⁷ Materials with low bio-availability are neutral; materials with high bio-availability may serve as food sources, toxins, or regulatory substances for biological organisms. For example, a toxic substance may be present at high concentration, but if it is bound up in a biologically inert un-reactive form, it will have low bio-availability and thus no toxic effect.

Fluoride is absorbed and enters the body fluids by way of the lungs or the gastrointestinal tract. However, not all ingested fluoride is absorbed. In parts of China and India where fossil fuels contain extremely large amounts of fluoride (up to 3,500 parts per million) fluoride may be absorbed in large quantities by way of the lungs.

Roughly 50 per cent of an absorbed amount of fluoride will be excreted in the urine during the following 24 hours and most of the remainder will become associated with calcified tissue (bones and teeth). Approximately 99 per cent of the fluoride in the body is associated with calcified tissues. Nevertheless, the fluoride of calcified tissues is not irreversibly bound.⁸⁸ The balance of fluoride in the body is maintained by the continuous uptake and release in bone and teeth. In the longer time, fluoride in the deeper regions of bone can be released during the process of the normal bone remodelling. Thus if the intake of fluoride were to increase or decrease on a chronic basis, the concentrations in the calcified tissues would eventually reflect the change. However, the quantity of fluoride that could affect biological processes is very small as most of the fluoride retained in the body is sequestered in the bones and teeth.

Acute Toxicity

Acute toxicity is the immediate effect of ingesting large doses of fluoride. The toxicity depends on many factors but of key importance are the amount ingested and the body weight of the individual. Clearly, a particular dose of fluoride is likely to have more serious consequences in a young child than in an adult. For this reason the toxicity of fluoride is usually expressed as the amount per kilogram of body weight.

Almost immediately after ingestion of a large dose, the person experiences nausea and upper abdominal discomfort, often accompanied by vomiting. Excessive salivation, mucous discharges from the nose and mouth, headache, sweating, diarrhoea and generalised weakness may or may not be present. If a potentially lethal dose is involved, neurological signs, including spasm of the extremities, tetany and convulsions, may develop.⁸⁹

The **probable toxic dose (PTD)** of fluoride is defined as: 'The minimum dose that could cause toxic signs and symptoms including death and that should trigger immediate therapeutic intervention and hospitalisation'.⁸⁸

The current definitive guide to PTD, based on the work of Dukes, Bayless and Tinanoff, quantifies the PTD as an oral fluoride dose of 5.0 mg/kg body weight.^{88, 90, 91}

Acute toxicity stemming from the ingestion of optimally fluoridated water is highly unlikely because of the enormous volume of water needed to provide a sufficiently high dose.⁸⁸ As discussed above, a dose of approximately 5mg/kg body weight may cause serious systemic toxicity, but this would require the ingestion of 50 litres of water fluoridated at 1mg/l (ppm) by a 1-year-old child and of 100 litres by a 5-year old child.

Young children are particularly at risk of ingesting potentially life-threatening doses of fluoride from oral care products. A standard tube of toothpaste contains about 125 gram of toothpaste (generally containing 1500 ppm fluoride); swallowing as little as one-quarter of a tube may be life-threatening for a one-year-old child. Similar dangers apply with fluoride mouth rinses and tablets. The risk of ingestion of these substances by children is compounded by the fact that these products are usually sold in containers, which do not have child resistant closures.

Fortunately, acute toxicity due to ingestion of fluoride containing oral care products is extremely rare and the safety of the very small amounts of fluoride present in milk and domestic water is evident.

The following table, Table 11.8 illustrates the amounts of various products which must be ingested in order to reach the potential toxic dose (PTD) of 5mg/kg.⁸⁸

Table 11.8
Fluoride content and probable toxic doses of oral care products

Product	Fluoride Formulation	Probable toxic dose (PTD = 5mg/kg)	
		1-year-old child (10kg)	5-6 year-old child (20kg)
Toothpaste	1500 ppm (1,5 mg/g) 1000 ppm (1.0 mg/g) 500 ppm (0.5 mg/g)	33 g 50 g 100 g	66 g 100 g 200 g
Rinse	Daily (0.05%NaF) (0.23 mg /g) Fortnightly (0.20%NaF) (0.97mg F/g)	217 ml 52 ml	434 ml 104 ml
Tablets	0.25 mg 0.5 mg 1.0 mg	200 tablets 100 tablets 50 tablets	400 tablets 200 tablets 100 tablets
Fluoridated milk	2.65 ppm (0.5 mg in 189 ml)	100 cartons (18.9 litres)	200 cartons (37.8 litres)
Fluoridated water	1 ppm	50 litres	100 litres

Chronic Toxicity

Since the onset of water fluoridation over 50 years ago in the United States, numerous claims of harm arising from the chronic ingestion of low levels of the ion have been made. The claims have included allergic reactions, cancer, birth defects, genetic disorders, disorders of various organ systems and other unwanted effects.

It is essential to allay the concerns of the public about any possible adverse effects of fluoride and to this end various authoritative bodies and organisations over the years have reviewed the literature dealing with many of the above claims.

The following summarises the literature on the topic of fluoride and possible adverse health effects.

Taves

Taves critically reviewed the literature, in 1979, on sensitivity reactions, genetic defects including Down's Syndrome and cancer and concluded that the 'data used to support the claims that fluoridation causes adverse effects in humans are not convincing'.⁹² He made the point that 'scientists are generally sceptical of important claims unless the data: (a) come from well controlled experiments designed to rule out bias and selection factors as causes; (b) are confirmed independently by others, and (c) make sense in the light of other knowledge'.

With such requirements to the fore any claims of adverse effect must be reviewed in such a light. This will require such approaches as systematic reviews of studies published in peer-reviewed publications.

Knox Report

A review of studies of cancer rates in relation to fluoridation of water supplies was published in 1985.⁹³ Conclusions reached were as follows:

There was no evidence that either fluoride occurring naturally in water, or fluoride added to water supplies, was capable of inducing cancer, or of increasing the mortality of cancer. Contrary conclusions were in the reviewers' opinion attributable to errors in data, errors in analytical technique, and errors in scientific logic.

The absence of demonstrable effects on cancer rates due to long-term exposure to either naturally or artificially elevated levels of fluoride in water, the large human populations observed, the consistency of the findings from many different sources of data in many countries led the reviewers to the conclusion that with respect to cancer the fluoridation of drinking water was safe.

The routine monitoring of public health was acknowledged as a means whereby the safety of fluoride could be ascertained and its continuation was recommended.

In 1991 Bucher et al reported 'equivocal evidence' for a link between high fluoride exposure and osteosarcoma in male rats (but not female rats nor male or female mice).⁹⁴ This finding was an instigating factor in the publication in the early 1990s, of three critical reviews of the literature dealing with the risks and benefits of chronic fluoride exposure.⁹⁵⁻⁹⁷

These reports dealt mainly with fluoride exposures associated with drinking water fluoride concentrations up to about 5 ppm. Certain gaps in our knowledge about the effects of fluoride on one or more biological systems or functions were identified and additional research was recommended.

Kaminsky et al

Kaminsky et al in 1990 summarised the knowledge of the benefits and risks of fluoride ingestion on the basis of evidence that was current at the time. The following summary points were made:

- The preponderance of evidence indicated that fluoride can reduce the incidence of dental caries and that fluoridation of drinking water can provide such protection. The fact that decay rates have also fallen in non-fluoridated areas is acknowledged and attributed to the exposure to fluoride sources other than drinking water.
- Moderate dental fluorosis occurs in 1 to 2 per cent of the population exposed to fluoride at 1mg/l in drinking water and in about 10 per cent of the population at 2mg/l; moderate/severe fluorosis occurs in variable percentages ranging up to 33 per cent of the population exposed to fluoride at 2 to 4 mg/l in drinking water. The issue of whether moderate or severe dental fluorosis represents an adverse health effect was still controversial.
- There was no evidence of skeletal fluorosis among the general US population exposed to drinking water fluoride concentrations lower than 4mg/l. Reports of crippling skeletal fluorosis associated with low concentrations of fluoride in drinking water in tropical countries have been attributed to other dietary factors. Two cases of crippling skeletal fluorosis associated with excessive consumption of fluoridated water and tea have been reported in the US. Fluoride intakes by these individuals were reasonably estimated to have exceeded 15 to 20mg per day for 20 years.
- There was no evidence of increased incidence of renal disease or renal dysfunction in humans exposed to up to 8mg fluoride per litre in drinking water.
- There was no evidence that chronic exposure to concentrations of fluoride reported to be > 2mg/l in drinking water increases human cancer mortality or incidence.

- There was no evidence that fluoride is genotoxic except in some in-vitro assays at cytotoxic concentrations.
- There was no in-vivo evidence that fluoride affects human cellular enzyme activities. Fluoridated drinking water at 5mg/l slightly increased renal enzyme activities in monkeys when ingested chronically for 18 months.
- There was no evidence that exposure of pregnant mothers to fluoride at up to 2mg/l in drinking water causes Down's Syndrome or other congenital malformations in offspring.

Children living in fluoridated areas or receiving fluoride supplements (0.5mg to 1.0mg per day) have a 1.5 to 3-fold margin of safety for moderate or severe dental fluorosis. A higher margin of safety (7- to 8-fold) exists for children living in non-fluoridated areas who do not receive fluoride supplements. The margin of safety over pre-clinical and clinical stages of skeletal fluorosis among adults living in fluoridated areas is 4- to 8-fold and 10-fold respectively; adults living in non-fluoridated areas have a 13- to 26-fold and 33-fold margin of safety from these effects.

United States Public Health Service Report

The conclusions reached in the USPHS report were summarised as follows:⁸⁸

- There is no detectable risk of cancer in humans associated with the consumption of optimally fluoridated water.
- Data from animal studies have not established an association between fluoride exposure, even extremely high and life-long exposure, and cancer.
- There is no indication that organ systems are affected by long-term, low-level fluoride exposure (although more research on human reproduction, for which there is a paucity of data, was recommended).
- Fluoride exposure is not associated with birth defects, including Down's Syndrome.
- Genotoxicity studies, which are highly dependent on the methods and the models used, have yielded contradictory results so that any possible effect of fluoride in humans and laboratory animals remains unresolved.
- The prevalence of dental fluorosis in the USA is higher now than in the 1940s, but there is disagreement about whether this condition is a toxic effect.
- Skeletal fluorosis has not been and is not a public health problem in the USA.

National Research Council

The National Research Council looked at the possible toxic effects of ingested fluoride in humans.⁹⁷ The conclusion was that the EPA's maximum contaminant level (MCL) of 4mg/L for fluoride in drinking water was appropriate as an interim standard. However, it recommended further research in the areas of fluoride intake, dental fluorosis, bone strength and fractures and carcinogenicity.

Since the publication of the above reports a number of reviews have been published.

Canadian Report

In 1999, the Ministry of Health in Ontario, Canada undertook a further review of the literature, published between 1994 and 1999.⁹⁸ This review provided an update of the 1996 Federal-Provincial Subcommittee concerning fluoride in the water supply, which had made two recommendations.

The maximum acceptable concentration (MAC) for fluoride in drinking water is 1.5 mg/l. This recommendation was based on a tolerable daily intake (TDI) of 122 micrograms / kg body weight for a child of 22-26 months. This TDI value was taken from a 1994 report produced under contract to Health Canada. The age 22-26 months is the period of greatest risk for the development of fluorosis in the anterior permanent teeth. An intake of 122 micrograms/kg body weight was considered to be unlikely to result in moderate to severe fluorosis.

If it is desired that water supplies be fluoridated as a public health measure for the prevention of dental decay, an optimal concentration of 0.8-1.0 mg/L should be maintained.

The 1996 report did not address whether or not water fluoridation produces appreciable benefits in the modern context, when caries rates in children are low and fluoride is obtained from many other sources.

The 1999 review addressed a number of topics including the mechanism of action of fluoride, the benefits and health risks of water fluoridation, the fluoride intake in Canada and the determination of optimal levels for the water supply. The main principle underlying this review was that dental public health interventions, particularly those aimed at total populations, must make a demonstrable contribution to the oral health-related quality of life of the recipients and avoid subjecting those recipients to risks which are not commensurable with the benefits obtained in terms of improved quality of life.

The main findings of this review in the areas of health risks are summarised below.

While fluoride is a poison in large doses, toxic levels cannot be achieved by drinking fluoridated water. Fluoride products should be kept out of reach of children since toxic amounts could be ingested via these sources.

Current studies support the view that dental fluorosis has increased in both fluoridated and non-fluoridated communities. Although largely confined to the 'very mild' and 'mild' categories, they are of concern insofar as they are discernible to the lay population and may impact on those so affected. Research is needed into the relative effects of dental decay and fluorosis on quality of life outcomes and community values regarding the balance between reductions in dental decay and increases in dental fluorosis associated with water fluoridation.

Skeletal fluorosis is a crippling disease associated with chronic exposures of over 10 mg of fluoride per day for at least ten years. Studies of bone mineral density have not detected changes consistent with the clinical picture of skeletal fluorosis from water containing levels of fluoride optimal for the reduction of dental decay.

Studies of the association between water fluoridation and bone fracture are largely ecological in design (i.e. studies in which a population rather than an individual is the unit of comparison; such studies are employed to generate a hypothesis rather than to test a hypothesis) and are thereby of limited value. In order to estimate any public health significance of small increases in hip fracture rates in elderly populations, more studies with better research designs are needed.

The few studies published during the period review (1994 to 1999) do not challenge earlier research showing that there is no reason to believe that exposure to fluoridated water increases the risk of cancer in bones or body tissues.

Studies from China claiming that children exposed to high levels of fluoride had lower IQs than children exposed to low levels were found to be deeply flawed and provided no credible evidence that fluoride obtained from water or industrial pollution affects the intellectual development of children.

As contemporary data were not available, recommendations regarding optimal daily intakes of fluoride were based on dose-response data published in the 1940s. Optimal intakes are those derived from water fluoridated at 0.8 to 1.2 ppm, assuming no other sources of fluoride except food. Actual total daily intakes were derived from amounts present in water, food, breast milk, air, soil and toothpaste. In Canada, actual intakes are larger than recommended intakes for formula-fed infants and those living in fluoridated communities.

The main recommendations of this report are summarised below. It must be borne in mind that these recommendations were made in the context of the Canadian situation, where the rate of dental decay in the child population is very low and where there is no significant difference between decay rates in children living in fluoridated areas and in non-fluoridated areas. In a community with low decay rates a careful assessment of the balance between reductions in dental decay and increases in dental fluorosis should be undertaken.

- While data on dose-response relationships between water fluoridation and dental decay rates are sparse, there is a suggestion that fluoridating water to 0.5 -0.6 ppm may be adequate in terms of achieving reductions in dental decay. Guidelines should be flexible to accommodate communities with different prevalence of dental decay and different values concerning the benefits and risks.
- If the maximum acceptable concentration of fluoride is to be maintained at 1.5 mg/l, efforts need to be made in communities at the upper end of the range to reduce exposure to other sources of fluoride.
- The main limitations of current research on the effectiveness of water fluoridation are its exclusion of adults and elderly and its failure to consider quality of life outcomes. Since water fluoridation is a total population strategy, its benefits to the population as a whole need to be documented.
- Research also needs to be undertaken to determine when and what level of dental fluorosis has a negative effect on those with the condition and the trade-offs the lay population is willing to make with respect to reductions in dental decay and increases in dental fluorosis.

University of West Florida

In May 2000, the University of West Florida reviewed the fluoride literature to assist the understanding of the potential environmental and human health impacts of fluoridation of water.⁸⁷ Again this review specifically excluded publications which were not scientifically valid.

With regard to risks associated with fluoride the following points were made. In laboratory in-vitro experiments the concentration of fluoride at which enzyme inhibition occurs is quite often a 100 to 1,000 times greater than the concentration that occurs in humans and such experimental inhibition of enzymes is not physiologically meaningful. Normal fluoride soft-tissue levels are in the micromolar range ($1.0 \mu\text{M} = 19$ parts per billion), whereas enzyme inhibition typically requires millimolar concentrations ($1.0 \text{M} = 19$ parts per million).

On the subject of cancer, reference was made to the International Agency for Research on Cancer (IARC) which in 1982 compiled data comparing cancer rates in regions with naturally or artificially fluoridated water to those regions with low fluoride levels. The IARC found no correlation of cancer rates with fluoride exposure.

In conclusion, a number of recommendations were listed:

- Epidemiological monitoring should continue to keep up-to-date information on the relationships among exposures from all major sources and the prevalence of dental caries and enamel fluorosis at specific stages.

- Basic laboratory and epidemiological studies should be undertaken to further the understanding of effects of fluoride on biomechanical properties of bone and on calcification of soft tissues should be supported.
- Clarification of the effects of metabolic and environmental variables on the absorption, retention, excretion and biological effects of fluoride with other elements and ions (Al, Mg, Ca) and how it affects their bio-availability requires further study.

York Review

In 2000 a 'Systematic Review of Public Water Fluoridation' was published.⁶⁶ The Chief Medical Officer in the Department of Health in England commissioned the University of York in conjunction with the University of Wales, Cardiff and the University of Leicester to 'carry out an up-to-date expert scientific review of fluoride and health'. A summary of the review was presented to the Forum and is available on the Forum's website: www.fluoridationforum.ie. The full report is available on the following website: www.york.ac.uk/inst/crd/fluores.htm

Four objectives were presented.

Objective 1: What are the effects of fluoridation of drinking water supplies on the incidence of caries?

Objective 2: If water fluoridation is shown to have beneficial effects, what is the effect over and above that offered by the use of alternative interventions and strategies?

Objective 3: Does water fluoridation result in a reduction of caries across social groups and between geographical locations, bringing equity?

Objective 4: Are there differences in the effects of natural and artificial water fluoridation?

The conclusions of this review were as follows:

- The best available evidence from studies on the initiation and discontinuation of water fluoridation suggests that fluoridation does reduce caries prevalence, both as measured by the proportion of children who are caries-free and by means of the dmft/DMFT. The degree to which caries was reduced was unclear from the data available.
- An effect of water fluoridation was still evident in studies completed after 1974 in spite of the assumed exposure to fluoride from other sources by the populations studied.
- The available evidence on social class effects of water fluoridation in reducing caries appeared to suggest a benefit in reducing the differences in severity of tooth decay between classes among 5 and 12 year old children. However, as the quality of evidence was low, the association between water fluoridation, caries and social class required further clarification.
- With regard to possible negative effects the effects on dental fluorosis were the clearest. There was a dose response relationship between water fluoride level and the prevalence of fluorosis. A rate of 12.5 per cent of fluorosis of aesthetic concern was noted in fluoridated areas.

- There was no evidence of an association between water fluoridation and cancers.
- With regard to other adverse health effects there was insufficient good quality evidence on any particular outcome to reach conclusions.
- The evidence on natural versus artificial fluoride sources was extremely limited and comparisons were not possible for most outcomes.

While this review was limited by the quality of the available research, strict criteria, based on a pre-defined hierarchy of evidence (A, B or C) were employed in the inclusion of studies and papers. (Level A: highest quality of evidence and minimal risk of bias. Level B: evidence of moderate quality and moderate risk of bias. Level C: lowest level of evidence and high risk of bias.)

Studies of efficacy were included if they were of evidence A or B. In order to allow the broadest search for evidence on potential adverse effects, studies of all levels of evidence were included. Such a selection system was necessary as the burden of proof had to be greater for something that was of benefit compared with that which might be harmful.

Fluoride and Bone Health

While the benefits of water fluoridation for dental health are widely accepted and substantiated, concerns have been raised about the effects of fluoride on bone mineral density and rates of fracture. However, epidemiological evidence associating water fluoride concentration with the incidence of hip fractures has been inconsistent.⁹⁹ Ecological studies that compare rates of fracture specific for age and sex between fluoridated and non-fluoridated communities have variously found that exposure to fluoridated water increases the risk of hip fracture¹⁰⁰⁻¹⁰², increases the risk of proximal humerus and distal forearm fractures¹⁰³, has no effect on fracture risk¹⁰⁴⁻¹⁰⁶, and decreases the risk of hip fracture.^{107, 108}

Ecological studies, however, have a major design flaw – they are studies in which groups of individuals or whole communities exposed to fluoridated water are compared with groups or communities not exposed, unlike epidemiological studies in which the unit of investigation is the individual and thus several confounding variables can be adjusted for, such as smoking, body weight and physical activity. In recent years a number of epidemiological studies have looked at fluoride and bone and will be summarised later in this chapter.

Osteoporosis

Osteoporosis is a disease characterised by low bone mass and micro architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk. It is the commonest bone disease worldwide. It may be primary, where it occurs post-menopause (Type 1) or in later years (Type 2) or secondary due to systemic disease or drug related.

The risk factors for the development of primary osteoporosis include genetic predisposition, hypogonadism, low body weight, cigarette smoking, excess alcohol, low dietary calcium, vitamin D deficiency, late menarche, irregular menstruation, early menopause, physical inactivity and high caffeine intake.

The diseases associated with secondary osteoporosis are: metabolic, endocrine, malignant, transplantation and connective tissue disorders. Drugs associated with this form of the condition are: excess thyroid hormone, anticonvulsant therapy, glucocorticoids, heparin and alcohol.

Osteoporosis is a major risk factor for fractures. The risk of developing a fracture as a result of osteoporosis depends on the amount and strength of bone, the rate at which bone is lost, and the type of fall. The common sites for the development of osteoporotic fractures are the hip, spine and wrist. The most serious of these is the hip fracture. There is an increase in fractures in women progressively from the age of 45 years.¹⁰⁹ Fracture of the hip is a major cause of morbidity and mortality in persons 65 years of age and older.

In 1990, there were 1509 hip fractures in the over 60 year olds; in 1999 there were 3504, by 2000 this figure had risen to 3821. Aside from the fact that one in five patients die within 6 months of the fracture occurring, hip fractures lead to serious disability. Many basic functions such as dressing, climbing stairs, walking and transferring are markedly interfered with following a fracture. This can result in loss of both confidence and independence and an increased risk of development of medical complications.

A previous fracture more than doubles a patient's risk of another spinal fracture. Fractures of the distal radius (Colles' fracture) occur most commonly in women between 45 and 65 years of age. All require immobilisation in plaster as outpatients. However, older patients, especially those living alone, will require hospitalisation, with the consequent disruption to daily activities and loss of independence.

Bone Mineral Density

Bone mineral density (BMD) is a well-established medical technique for the measurement of bone mass, confirmation of osteoporosis and determination of the risk of fragility fractures. BMD correlates well with the probability of fracture in people with osteoporosis and improvements in patients' BMD following treatment for osteoporosis correlates well with a reduced rate of fracture.

BMD increases during childhood and adolescence, peaks in the third or early in the fourth decade of life and declines progressively thereafter, with a sharp decline in the early postmenopausal years.^{110, 111} The World Health Organisation defines osteoporosis as a bone mineral density of more than 2.5 standard deviations below the average value for bone mass in young adults (T score), when measured by Dual Energy X-Ray Absorptiometry (Dexa) or an osteoporosis related fracture.¹¹²

The normal peak bone mineral density in the following areas is:

Lumbar spine (L1 to L4): $1.031 \pm 0.130 \text{ g/cm}^2$

Hip and neck of femur: $0.833 \pm 0.117 \text{ gm/cm}^2$

In osteoporosis the BMD in the neck of femur (hip) is $< 0.55 \text{ gm/cm}^2$

A number of steps may be taken to prevent osteoporosis: adequate dietary calcium and vitamin D, reduced alcohol intake, smoking cessation, weight bearing exercise and appropriate medications.

Criteria have been developed to assess whether a risk factor (in this case fluoride) actually causes a disease (in this case bone fractures or a reduced BMD). These criteria depend on accumulating a large and consistent body of evidence, indicating there is a high probability that the risk factor is the cause of the disease.¹¹³

Trials have shown that high doses of sodium fluoride substantially increased vertebral bone density, but this effect was not associated with lower rates of spinal fractures.¹¹⁴ This effect has only been seen when intake has been substantially higher than would be expected from fluoridation of water. Sodium fluoride as an anabolic substance was used in the past in the management of osteoporosis, but is no longer licensed in Ireland and Europe. It prolongs bone remodelling if given in twice the therapeutic dose. Experimental studies have shown that fluorotic bone is more resistant to compressive forces, but more easily fractured by torsional strains. Moderate doses of fluoride have been shown to increase bone strength in experimental animals and high doses of continued exposure decrease strength.

Hillier et al

In 2000 Hillier et al published the results of a population based case-control study, which explored the relationship between fluoride ingestion and the risk of hip fractures.¹¹⁵ It was demonstrated that the frequency of hip fractures correlated with low body-mass index and physical inactivity. After adjustment for these and other confounders, the investigators could not find an increased risk of hip fracture among individuals with lifetime exposure to water containing fluoride at concentrations greater than 0.9 mg/litre. The authors also employed an ecological approach and compared the risk of hip fracture among residents living in a town with natural high concentrations of fluoride ($> 1 \text{ mg/l}$) in their drinking water, with residents of other communities of the county where fluoride concentrations were very low ($< 0.2 \text{ mg/l}$). Here again those consuming naturally fluoridated water were at no greater risk of hip fracture.

Phipps et al

Phipps et al in 2000 published the results of a multicentre prospective study of 9,704 women on risk factors for osteoporosis and fractures.⁹⁹ This study demonstrated that women who had continuous exposure to fluoride had significantly higher bone mineral density of the lumbar spine, femur, but significantly lower density of the radius. After adjustment for

potential confounders, women with continuous exposure had a 31 per cent reduction in risk of hip fracture and a 27 per cent reduction in risk of vertebral fracture.

The authors made the point that as the burden of osteoporosis is largely due to fractures of the hip, the reduced risk of fracture attributed to fluoride exposure may be one of the most cost-effective methods for reducing the incidence of fractures related to osteoporosis. They also pointed out that the development and validation of a fluoride biomarker is an essential next step in the continued study of the relation between fluoride and skeletal health.

York Review

As discussed above no evidence of an elevated risk of fractures attributable to using the optimal level of fluoride in drinking water was found in the systematic review by McDonagh et al.⁶⁶

Demos et al

Demos et al in 2001 reviewed the research on the effects of fluoride on bone published since 1991.¹¹⁶ They looked at 33 studies, which included 6 animal studies and 27 human studies of various types (seven ecological, three cross-sectional, three cohort studies, one case-control studies and 12 clinical trials).

The reviewers concluded that there was a substantial body of epidemiological evidence in studies (cross-sectional, cohort and clinical trials) in different geographical areas and in different populations which showed that drinking water fluoridated at up to 1 ppm does not have an adverse effect on bone strength, bone mineral density or fracture incidence.

Chachra et al

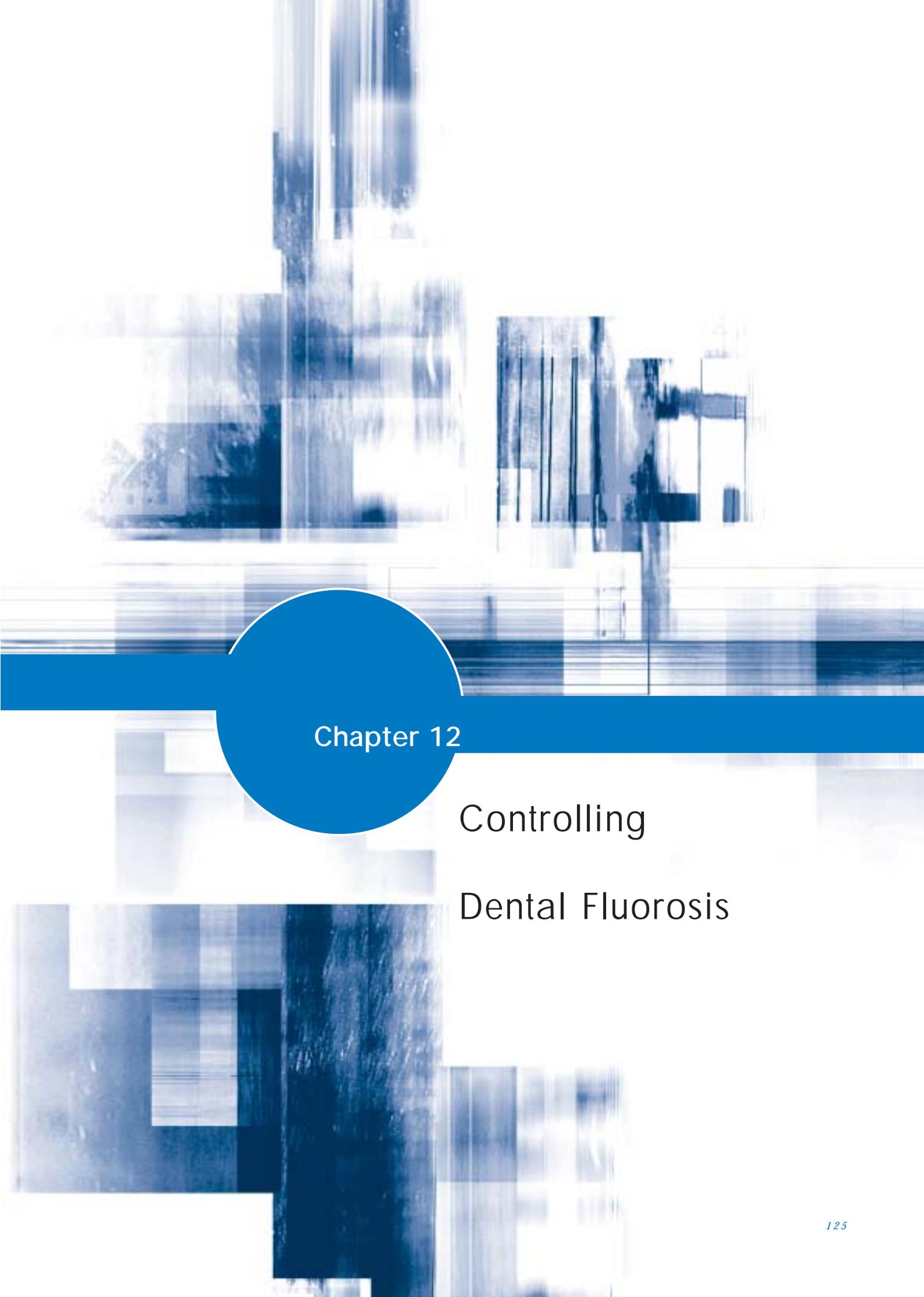
This was a study of bone quality in fluoride-free Montreal and fluoridated Toronto, among patients who underwent total hip replacements as a result of osteoarthritis. While the average amount of fluoride incorporated in the bone was significantly greater in those who resided in Toronto (fluoridated), there was no suggestion that long-term ingestion of fluoridated water in itself had an adverse affect on bone quality.¹¹⁷

Conclusion

Several ecological studies have found that rates of hip fracture are higher in communities with fluoridated drinking water compared with communities without fluoridation. These studies however have not controlled for several factors known to be associated with rates of fracture, including the use of oestrogen, smoking and body weight.

Epidemiological studies on the other hand have shown that long-term exposure to fluoride does not have an adverse effect on bone strength, bone mineral density or fracture incidence.⁶⁶

The use of fluoride in the treatment of osteoporosis was referred to above. The use of high doses of fluoride in the treatment of osteoporosis is no longer a therapeutic option. However, the role of low doses of fluoride, as is obtained in drinking water, is the subject of a systematic review.¹¹⁸



Chapter 12

Controlling
Dental Fluorosis

12 Controlling Dental Fluorosis

Introduction

An assessment of the relative benefits and risks of water fluoridation was described in Chapter 11. On the basis of such an assessment it is evident that water fluoridation continues to contribute to the control of dental decay and that there is an additive effect where water fluoridation and fluoride toothpaste are used together.

The best available and most reliable scientific evidence indicates that the general health of the population is not adversely affected by the fluoridation of public water supplies. However, a recognised and long-acknowledged side effect of fluoridation is an increased prevalence of dental fluorosis. Dean regarded an increased prevalence of fluorosis at the very mild/mild and questionable grades as an acceptable risk when weighed against the benefits to oral health that would accrue from the introduction of this public health measure. However, since the time of Dean other fluoride containing products for caries prevention have become more widely available and there is now clear evidence that fluorosis prevalence has increased since Dean's time in the United States and elsewhere. As outlined in Chapter 11 there is also evidence that the levels of dental fluorosis have increased in Ireland in recent years.

The purpose of this chapter is to identify the risk factors for dental fluorosis and to outline the strategies which may be adopted for reducing the prevalence of dental fluorosis in the Republic of Ireland.

Dental fluorosis has been defined as 'a dose response effect caused by fluoride ingestion during pre-eruptive development of teeth'. This change in the enamel is characterised by altered appearance of the tooth ranging from fine white lines (which are difficult to see), to pitting or staining of enamel. The following photographs show the various levels of fluorosis and normal teeth. Refer to photographs.



Normal



Questionable



Very mild



Mild



Moderate



Severe

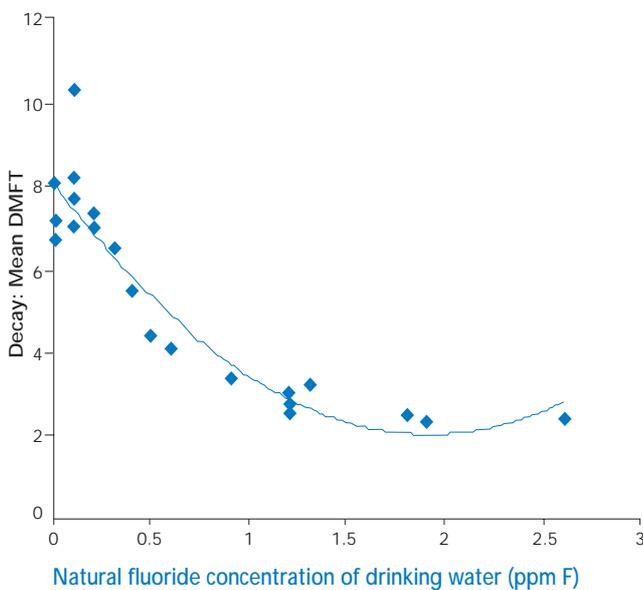
The relationship with fluoride became known in 1931, and the term 'dental fluorosis' became accepted terminology in the mid-1930s. Following the identification of fluoride as a cause of mottled enamel, Dean developed a standard of classification of mottling in order to record quantitatively the severity of mottling (see Table 11.5).

An investigation by Dean, known as the 21 Cities Study, resulted in the identification of the lowest concentration of fluoride in public water supplies at which caries was clearly inhibited and where the level of dental fluorosis in the community was considered acceptable. The first graph below shows that the occurrence of dental decay experience drops sharply as the fluoride concentration rises toward 1.0 ppm. The second graph demonstrates the levels of dental fluorosis at increasing concentrations of fluoride.

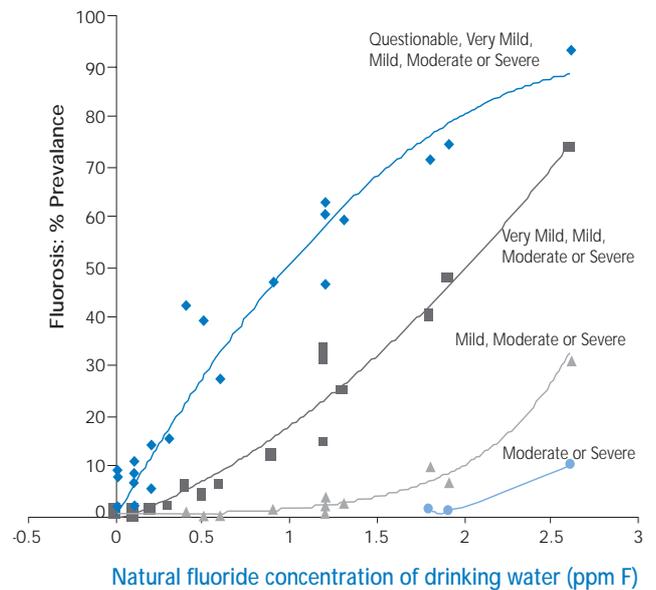
While Dean described the 'questionable' grade of fluorosis separately in his reports, Burt and Eklund suggest that if 'questionable' fluorosis had been included in the prevalence figures, the 'acceptable fluorosis' may have been set at concentrations lower than 1.0 ppm.¹¹⁹

The second graph (cumulative graph), demonstrates the levels of fluorosis that would be expected at the varying levels of fluoride in the drinking water. At a level of 1 ppm of fluoride in the drinking water one would expect to see 1 per cent mild fluorosis, 19 per cent very mild and 31 per cent questionable fluorosis; this gives cumulative total of 51 per cent with some degree of fluorosis and 49 per cent with no change in the appearance of the tooth enamel.

Relationship between Natural Fluoride Levels and Dental Decay



Relationship between Natural Fluoride Levels and Dental Fluorosis



Dean's Graphs

Based upon Dean's results, and as may be seen from looking at the DMFT graph, if fluoride levels in the water supplies were at 0.7 ppm, the average DMFT would be at 4.45 instead of 3.44 at 1.0 ppm. In the case of fluorosis, at 0.6 ppm, the percentage affected by questionable or very mild fluorosis would be 38 per cent compared with 51 per cent at 1.0 ppm.

It is important to note that these data were collected when sources of fluoride were largely confined to water supplies. Nowadays, however, with the widespread use of fluoride toothpastes, the relative differences of fluoridating water between 0.6 ppm and 1.0 ppm from the point of view of the benefit (reduction in dental caries) and risk (fluorosis) is likely to be less.

Risk Factors for Dental Fluorosis

In an assessment of the risk of dental fluorosis, the upper central incisors are the index teeth of choice for consideration. As Evans and Stamm note, 'The control of dental fluorosis with special reference to the effects on upper central incisors is, from a practical standpoint, virtually synonymous with control of fluorosis in the dentition as a whole.'¹²⁰ It is now well established that dental fluorosis in the upper permanent incisor teeth is associated with excessive intake of fluoride in the period from birth to 5 years, when the crowns of these teeth are forming and maturing prior to their appearance in the mouth at about age 7 to 8 years, (see Tables 3.1 and 3.2 in Chapter 3). The most critical period for developing fluorosis on the permanent central incisors has been variously estimated to be between 22 and 25 months of age or between 15 and 24 months for boys and 21 and 30 months for girls.¹²¹ It would appear that the risk of dental fluorosis in the maxillary central incisors is low in the first 15 months of life. However, excessive fluoride ingestion during this time may be associated with an increased risk of fluorosis in the primary dentition.

Fluoridated Drinking Water

Excessive intake may be from drinking water where technical problems with dosing in smaller plants may result in fluoride levels over and above the upper limit of 1 ppm.

Infant Formula

There is no evidence that the ingestion of infant formula reconstituted with fluoridated water is a risk factor for any condition other than dental fluorosis of the anterior permanent teeth. A case-control study by Osuji et al has suggested that it was only a risk factor when the formula was consumed for a period of thirteen to twenty four-months.¹²² The contribution of infant formula reconstituted with fluoridated water to the development of

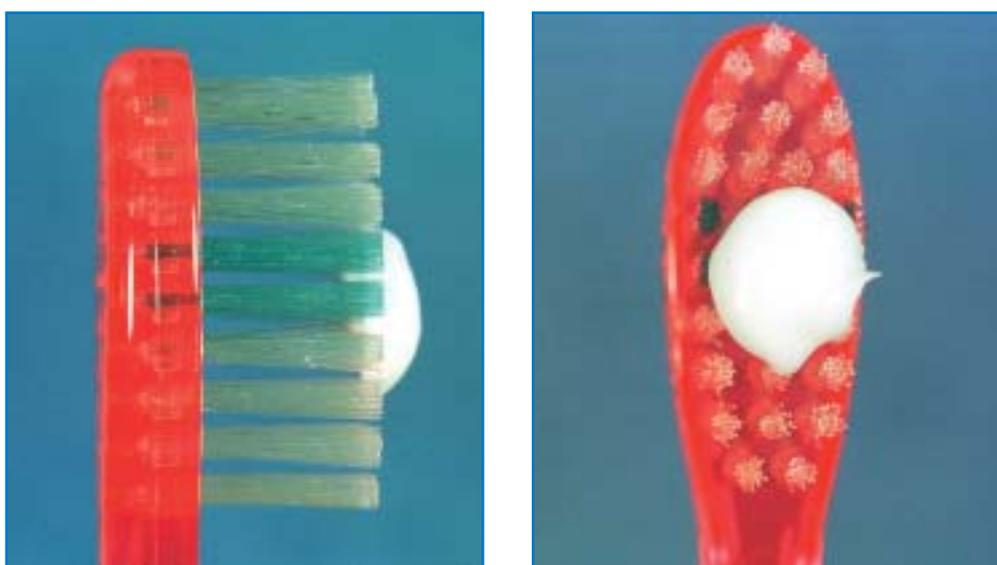
dental fluorosis in Ireland is the subject of a risk assessment analysis recently undertaken by the Food Safety Authority of Ireland (FSAI). A full report of this study may be found in Appendix 18. A summary of the report is available as an insert in the Forum's Executive Summary.

This assessment will take into account the recommendation concerning the downward adjustment of the fluoride content in public water supplies and the resultant reduction in dental fluorosis that can reasonably be expected.

It will also take account of the bioavailability of fluoride ingested by infants. If appropriate, changes to the recommendations regarding appropriate infant feeding practices will be made in the light of the findings of this risk assessment. The ongoing national survey of children's dental health will also examine the association between infant feeding practices and dental fluorosis. The results of these studies should be available in 2002. Another study is underway which is looking at the prevalence of dental fluorosis in primary teeth.

Fluoride Toothpaste

There is now clear evidence that the inappropriate use of fluoride toothpaste during infancy and early childhood is associated with the development of dental fluorosis in permanent incisor teeth. This can be due to parents beginning to brush their babies' teeth with toothpaste at too early an age (before 18 months to 2 years when the baby molar teeth appear in the mouth) when children may have not yet developed an ability to adequately rinse out their mouths but instead swallow most of the toothpaste put on the brush (especially if the taste is pleasant). Secondly, the amount placed on the brush in most cases exceeds the recommended amount (only a small pea size). The following photographs show a pea size amount of toothpaste on a child's toothbrush



The amount of fluoride in toothpaste varies between 500 ppm and 1,500 ppm. Table 12.1 below lists the corresponding amounts of fluoride in milligrams for each toothpaste concentration assuming the recommended small pea size amount (0.25mg) is used.

Table 12.1

Recommended Amount of Toothpaste and its Fluoride content

ppm F Toothpaste	Amount of F in pea sized (0.25 g) amount of toothpaste
500ppm	$0.25 \times 0.5 = 0.125 \text{ mg F}$
1,000ppm	0.25 mg F
1,450ppm	$0.25 \times 1.4 = 0.36 \text{ mg F}$
1,500ppm	$0.25 \times 1.5 = 0.375 \text{ mg F}$

In a recent study in Cork (EU Biomed Flint Project) it was found that 60 per cent of the 1½ to 2½ year old children, who participated in the study, swallowed between 70 per cent and 100 per cent of the toothpaste placed on the brush. The results of this study are included in the final report to the EU and will be published shortly. The amount of fluoride ingested will depend on the concentration of fluoride in the toothpaste and the amount placed on the brush.

Toothpaste with 1,500 ppm F

If an infant of 1½ years weighing 11 kg, swallowed a pea-sized amount of fluoride toothpaste, containing 1,500 ppm, the amount ingested on a body weight basis would be 0.034 mg/kg body weight.

An infant weighing 7 kg, swallowing the same amount would ingest 0.054 mg/kg body weight. If this swallowing occurs each time the teeth are brushed, the amount swallowed is potentially quite considerable, for children brushing more than once a day.

Toothpaste with 1,000 ppm

If an infant of 1½ years weighing 11 kg, swallowed a pea-sized amount of fluoride toothpaste, containing 1,000 ppm, the amount ingested on a body weight basis would be 0.023 mg/kg body weight.

An infant weighing 7 kg, swallowing the same amount would ingest 0.036 mg/kg body weight.

Toothpaste with 500 ppm

If an infant of 1½ years weighing 11 kg, swallowed a pea-sized amount of fluoride toothpaste, containing 500 ppm, the amount ingested on a body weight basis would be 0.011 mg/kg body weight.

An infant weighing 7 kg, swallowing the same amount would ingest 0.018 mg/kg body weight.

Fluoride Supplements

Fluoride supplements are a risk factor for fluorosis in young children when used inappropriately and not conforming to appropriate dosage schedules. However, the use and availability of fluoride supplements in Ireland does not appear to be an issue.

Fluoride Mouth Rinses

The inappropriate use of fluoride mouth rinses can cause fluorosis. However, as these rinses are not generally recommended for children less than six years of age, this should not be a contributory factor.

Strategies for Reducing Dental Fluorosis

Water Fluoridation Process

As discussed in Chapter 9, the fluoride level in drinking water should be less than 1 mg/litre or 1 part per million (ppm) to comply with the Drinking Water Regulations 2000. The Health (Fluoridation of Water) Act Regulations require that the level of fluoride be kept within a range of 0.8 and 1.0 parts per million. The technical requirements of staying within this range are very demanding, especially in the case of smaller water treatment plants. The fluoride monitoring results indicate that the levels of fluoride can be higher than desirable from some of these plants.

In order to avoid the risk of over-exposure it may be necessary to suspend fluoridation of some small supplies, pending the elimination of these small plants as a consequence of the regionalisation of water supplies.

The current Health (Fluoridation of Water) Act Regulations, based on Dean's work in the 1940s, specified an optimal level of 1 ppm. The data used were based on the fluorosis level at a number of fluoride levels: 0.5, 0.7, 0.9 and 1.2 ppm. When Dean's work was compared with data from more recent surveys it was found that contemporary data did not replicate the characteristic curve evident in Dean's studies. This led to the conclusion by Heller et al, that little decline in caries levels was observed between 0.7 and 1.2 ppm fluoride, while an increase in dental fluorosis was seen at this level of fluoride. They suggested on the basis of this finding that a suitable trade-off between dental decay and fluorosis appears to occur around 0.7 ppm.¹²³

Locker in his review of the risks and benefits of water fluoridation made the point that re-examination of the early dose response data suggests that levels as low as 0.6 ppm would have achieved approximately the same reduction in the prevalence of dental decay, and that new and contemporary guidelines are required to take into account the changing prevalence of dental decay, access to other sources of fluoride, and contemporary concerns with the cosmetic effects of fluorosis. He also points out that while dental fluorosis has not been viewed as a public health problem in the past it may become so in the future.⁹⁸

In Ireland in 2001, against a background of exposure to multiple sources of fluoride and changes in the rates of dental decay and dental fluorosis, on both a population and an individual level, it is considered appropriate to redefine the optimal level of fluoride, taking into account these altered circumstances.

Lowering the fluoride level in drinking water to between 0.6 to 0.8 ppm will be sufficient to bring about meaningful reductions in dental decay while reducing the risk of developing fluorosis. The consumption of water with this level of fluoride in conjunction with the continued use of fluoride toothpaste would mean that the recognised additive effect of using these two sources of fluoride would be maintained. In this respect, the oral health of the population as a whole would be maximised.

Further work is required in order to establish the relationship between the effectiveness of fluoride toothpaste combined with water fluoridation at 0.6 to 0.8 ppm.

Infant Feeding

Formula Feeding

As human milk is the natural choice of food for infants, manufacturers attempt to replicate this 'gold standard' food for infants who are not breast-fed. The various infant formulae on the market are controlled by EU compositional guidelines.¹²⁴ Infant formula made from cows' milk may be whey- or casein-predominant (proteins). The cows' milk protein in whey-predominant infant formula is altered in an effort to reflect the composition of breast milk, while the protein in casein-predominant formula maintains its similarity to cows' milk. It is generally recommended that the infant who is not breast-fed should be given a whey-predominant formula as casein inhibits iron absorption more than whey.¹²⁵

It is accepted that there are very few situations where bottle-feeding is clearly advantageous over breast-feeding; bottle-feeding can be associated with a number of common problems, including inappropriate choice of product, inappropriate concentration of feeds, addition of solid foods to bottles and inadequate hygiene during preparation. Bottle-feeding does not protect against infection in the way that breast-feeding does.

Formula milks are produced either in dried powdered or ready-to-feed format. An increased risk of obesity has been reported in infants fed on formula reconstituted from dried powder, probably due to errors in the mixing process.¹²⁶

Powdered formula is reconstituted with boiled drinking water: a measured amount of powder is added to a measured amount of water: 28 mls/1 fluid ounce of water to one scoop (approx. 4.5 gram powder); the mixture is shaken to dissolve the powder.

The ready-to-feed formula is sold in supermarkets in tetra pack cartons similar to milk or juice cartons. It has a long shelf life and once opened will keep in the fridge for 24 hours. Products available in Ireland are manufactured in other member states. An analysis of a number of six ready-to-feed formulae performed in the Oral Health Services Research Centre in UCC showed that the fluoride content was minimal.

It is recommended that parents continue to reconstitute infant formula with boiled tap water. Many of the brands of bottled water available in Ireland are not suitable for use in the reconstitution of infant formula due to the presence of salt and other substances which may be harmful to infants and young children.

The use of ready-to-feed infant formulae which are manufactured in non-fluoridated areas in the EU, for all or some of an infant's daily feeds, would reduce the amount of fluoride ingested as there is a negligible amount of fluoride in these preparations.

As mentioned above the Food Safety Authority of Ireland has investigated the overall contribution to the development of fluorosis attributable to infant formula. The Authority has concluded that the risk of moderate dental fluorosis of the primary and permanent teeth is very low in exclusively formula-fed infants aged 0 to 4 months residing in areas in which the level of fluoride in water does not exceed the statutory limit.

Breast-Feeding

The first year of life is a unique growth period during which infants triple their birth-weight and double their surface area. Nutrition at this time is therefore crucial in not only sustaining the growth of the infant, but in influencing the future health and well-being of the child.

Nature has provided mankind with an infant food which is produced with the needs of the young infant to the fore and, as such, breast-feeding is a key public health measure which offers benefits to both mother and infant.¹²⁷ Health benefits derived from breast-feeding include protection against gastroenteritis, respiratory infections, otitis media (middle ear infections) urinary tract infections and diabetes mellitus for the infant, and pre-menopausal breast, ovarian and endometrial cancers for the mother.^{128, 129}

Breast milk provides passive immunity for the baby and also enhances the benefits from immunisation through an increased active immune response.¹³⁰

However, the rate of breast-feeding in Ireland is low. In 1993, 34 per cent of mothers were breast-feeding on discharge from hospital. In the Euro-Growth Study, in 22 European

centres from 1992 to 1996 of a mixed socio-economic group of infants from birth and throughout the first year of life, the lowest level of breast-feeding was recorded in Ireland.¹³¹ Although 44 per cent of mothers wished to breast-feed, at age one month only 26 per cent were continuing to do so.

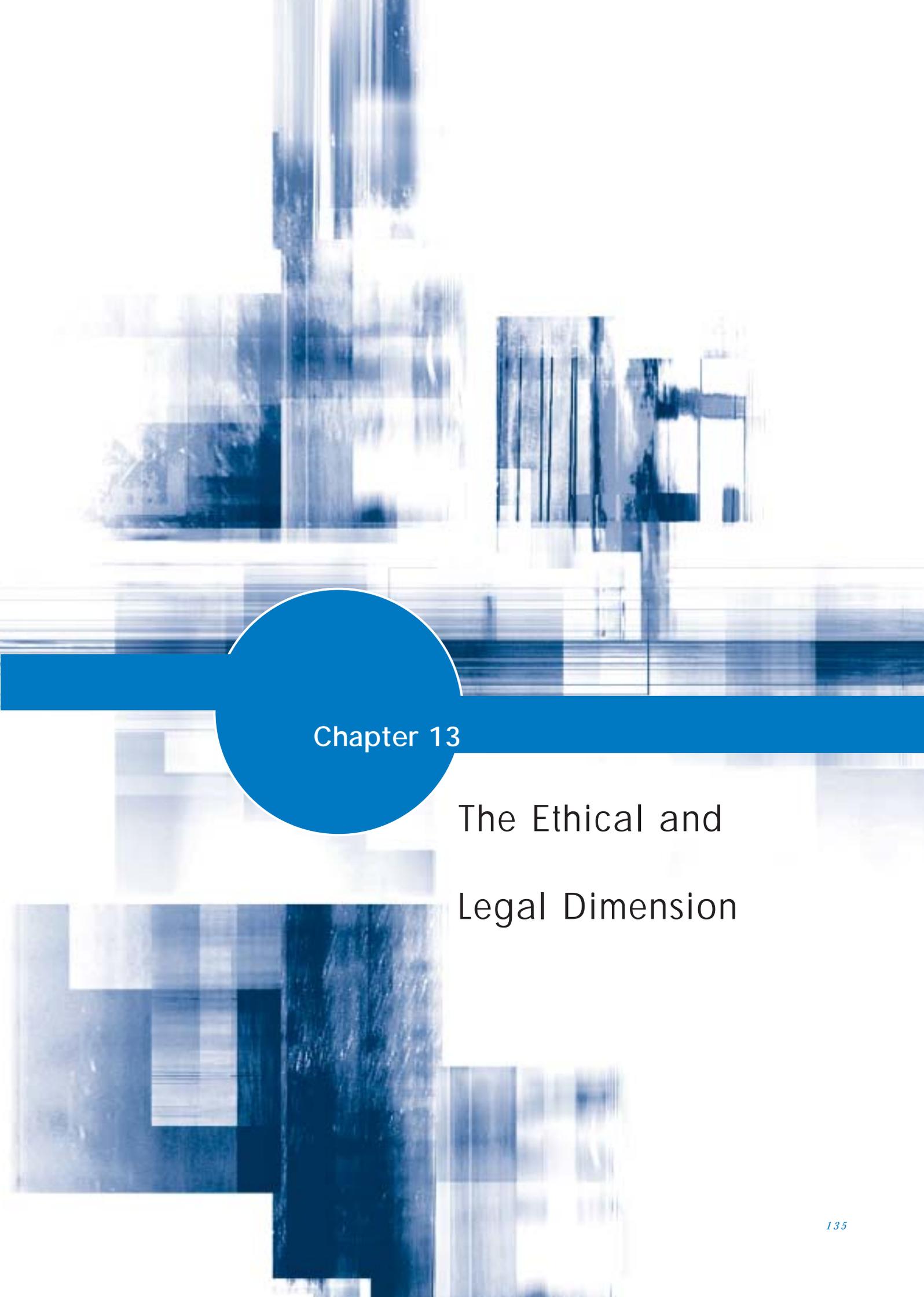
Cultural norms, such as attitudes to breast-feeding, media representations of artificial as 'normal', along with the relative lack of facilities provided in public places for mothers to feed their infants are likely to influence the choice to breast-feed. The short duration of maternity leave from the workplace and the lack of family friendly work schedules are other important influences on breast-feeding.

As part of the health promotion policy of the Department of Health and Children breast-feeding is recommended. Human breast milk of mothers resident in both fluoridated and non-fluoridated areas contains very low levels of fluoride. An increase in the rate of breast-feeding in this country would contribute significantly to a reduction of the occurrence of dental fluorosis. However, it is recognised that the use of formula feeding will continue to be the preferred choice for many parents.

Fluoride Toothpaste

The Forum recommends the continued use of fluoride toothpaste in fluoridated and non-fluoridated communities because of the additive benefit from the combination of fluoridated water and toothpaste. However, in order to minimise the risk of dental fluorosis the following is recommended:

- Parents should be advised not to use toothpaste when brushing their children's teeth until the age of 2 years. Prior to this age parents can brush their children's teeth with a toothbrush and tap water. Professional advice on the use of fluoride toothpaste should be sought where a child below 2 years of age is considered to be at high risk of developing dental decay.
- Parents should supervise children aged 2 to 7 years when brushing their teeth and should ensure that only a small pea sized amount of fluoride toothpaste is used and that swallowing of the paste is avoided. See photograph on page 129.
- The use of paediatric toothpastes with low concentrations of fluoride requires further research before the Forum can recommend their use.
- Guidelines for the use of oral health care products in childhood should be developed for use by all those involved in advising members of the public on health care matters. The Expert Body will have responsibility for the development of these guidelines.



Chapter 13

The Ethical and
Legal Dimension

13 The Ethical and Legal Dimension

Two presentations were made to the Forum which dealt with the relationship between the State and the individual and the reconciliation of the norms of welfare and paternalism with those of autonomy, privacy, bodily integrity and human dignity. These may be seen in Appendix 17. These presentations reflected the legal position at the time they were presented to the Forum and have not been altered to reflect any changes made since then. This is a complex area, the detailed treatment of which the members felt did not lie within the remit of the Forum. Nonetheless, because of the many references by members of the public to ethical matters and their obvious importance, the Forum was concerned that some consideration should be given to such matters. Hence, it invited the presentations referred to, and it set up a Sub-Group which reviewed the information presented and consulted with an expert in the area of ethics, Dr Richard Hull. Three key questions were posed by the Sub-Group and are presented below with the answers received, and these reflect the outcome of its deliberations.

Question 1

Does the addition of fluoride to drinking water pose any particular ethical problem?

Answer

Even though fluoride is in piped water, there is still an element of choice. People can choose not to drink tap water. Admittedly the choice is not an easy one, and if the State were concerned about real choice, then consideration would have to be given to supplying an alternative source of water.

Question 2

What about the breaching of bodily integrity and interference with autonomy?

Answer

The addition of fluoride to the water supply is a paternalistic intervention by the State to safeguard the dental health of its citizens. Health in general is seen as an area where paternalistic State intervention is justifiable, and in terms of oral health, the poor dietary habits of the Irish people could be seen as a justification for taking a paternalistic approach. The State makes other interventions which could be seen to breach bodily (and mental) integrity in a much more serious manner, e.g. education. Therefore, the degree of infringement of bodily integrity by fluoridation is relatively minor.

However, if more weight were to be given to autonomy, then a programme of oral health education could be introduced in conjunction with fluoridation, until the education alone could take over.

Question 3

What about the area of uncertainty in science, where it can never be stated categorically that something is completely safe?

Answer

Then it comes down to risk versus benefit. Does the benefit outweigh the risk sufficiently to allow that risk to be tolerated? If the precautionary principle were always followed, then nothing would ever be done. From an ethical viewpoint, risk can be justified if the benefit significantly outweighs the risk.

The York Report, in which it was reported that the benefit of water fluoridation was less than had been previously thought, was referred to.⁶⁶ Gaps in our knowledge in relation to fluoride toxicity were highlighted, particularly in relation to young babies and those with renal problems. On the issue of toxicology, the point was made that if conclusive scientific evidence of harm became available, then the ethical position would alter.

Dr Hull provided the following comment on the topic of water fluoridation:

'Theoretically, the issue of fluoridation unearths a potential conflict of values, between freedom and autonomy on the one hand, and welfare and paternalism on the other. Having said that, it really does seem to depend on one's point of view. For example, those in support of fluoridation could argue that health promotion through fluoridation is a condition of autonomy rather than a violation of it. Different sympathies can, rather obviously, lead to different conclusions. In what follows, I will assume for simplicity that fluoridation is proven to be beneficial. I will outline two potential moral backdrops from which one can approach the issue in the hope that it will both contextualise the debate and draw out some points for further discussion.

One way of looking at the issue of fluoridation is from the libertarian side of liberalism or, at least, a version of it. The libertarian tends to start with a very negative idea of freedom. Freedom is seen as Hobbes saw it, as the absence of external human constraints. On this model then, you are free as long as nobody is interfering with you. Freedom is all about being left alone. This, in turn, implies a strong moral emphasis on negative rights (rights that prohibit being interfered with as opposed to positive rights to assistance).

A strong emphasis on negative rights tends to go hand in hand with a (deontological) belief that doing harm is in some sense morally worse than allowing it. Negative rights against harmful intervention naturally seem to rule out doing harm rather than allowing it. To argue that allowing harm (failing to fluoridate) can be as bad as doing it would be to entertain the possibility of positive rights to assistance, which, on the libertarian idea of freedom, have no grounding. Positive rights to assistance would also entail a much more comprehensive State apparatus so as to provide that assistance. The worry here is that a more comprehensive State might begin to make decisions about what assistance we really need (like fluoride in our water or encouragement to live in a particular way). That, by definition of this account, is a violation of our freedom.

Again, the emphasis here is on being left alone. The core values of this position are freedom and autonomy. Substantive notions of equality don't really get a look-in since they would involve State interference (redistribution) which detracts from our freedom. There is a deep worry that State interference other than to protect our negative rights will inevitably lead to 'the evil of allowing others to constrain you to what they deem is good'. I think that that worry is implicit in many of the objections to fluoridation.

Another way of looking at the issue of fluoridation is from a version of a welfare liberal perspective. A welfare liberal perspective can share J.S. Mill's deep worry but tends not to hold such a negative view of freedom. It can concede that freedom requires positive conditions, such as a certain level of health, education and economic well-being. The idea is that freedom isn't just about being free from interference, it is also about being free to do things (and our choices about what we do tend to be very limited if we are economically deprived, uneducated or in poor health).

Along with positive conditions for freedom come positive rights to assistance; rights to things that enable us to be free. Given the value accorded to a certain minimum standard of human welfare on this account, it follows that failing to provide for that standard is morally reprehensible. This reflects a more consequentialist position that allowing harm can be as bad as, or worse than, doing it (because of the consequences). Moreover, such a position is consistent with limited paternalism; the State acting positively for the greater good of society rather than simply protecting rights to non-interference.

Limited paternalism creeps in here because of the different combination of values. Autonomy weighs in with a more positive notion of freedom (a notion that could be said to be a fundamental condition of autonomy for many). In turn, autonomy and freedom are joined by an ideal of (re)distributive justice (whether based on equality, priority or sufficiency). The combination of these values allows for autonomy to be limited to a certain extent for the sake of freedom and justice.

This is also where the idea of proportionality can be seen to take a front seat. John Rawls argues, for example, that we need to strike a balance between potentially conflicting values. He calls that balance "reflective equilibrium". Our deep worry then (if we have it) has to be weighed against considerations of freedom and justice.

What do the two approaches have to say on the issue of water fluoridation? I will consider two arguments in favour of fluoridation, the health argument and the safety argument. The health argument, that 'the public health goal of reducing tooth decay in the community is fostered', would be unlikely to go down very well with a libertarian approach. The idea of a government deciding what is in the interests of its citizens and acting accordingly could be said to be unacceptably paternalistic, involving a compromise of freedom, autonomy and bodily integrity. On the other hand, the welfare liberal might ask 'at what price autonomy?' The (consequentialist) goal of reducing tooth decay in the community could very well be seen to justify the associated reduction of autonomy in this case. Indeed, there could be said to be stronger arguments in favour of paternalistic intervention when health is at stake than there are when, for example, life-style choices are affected (assuming that

having bad teeth is not a life-style choice). That is because the slice of autonomy taken away in the latter case tends to be valued more highly than that in the former case (for example, we tend to defer to a doctor's prognosis far more readily than we do to a politician's).

Another (related) argument that I think is worth considering is the safety argument. If it is true that, in failing to fluoridate, we 'impose actual deaths and the risk of death on children', then the idea of compromising a little freedom, autonomy and bodily integrity so to arrest that situation is compelling. (I defer here to BFS evidence regarding the North Western Health Region in 1985.) Indeed, it should even be compelling to the libertarian since, at root, the State is justified through its ability to protect its citizens. Even from a libertarian perspective, then, one could argue that preventing child death, in a similar way to repelling foreign aggressors, is a way of protecting our negative rights.

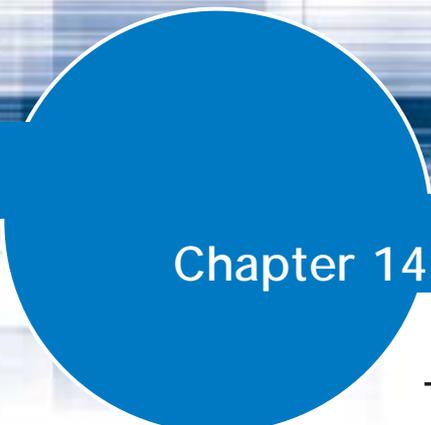
It is perhaps worth remembering that government, by its very nature, is paternalistic to some degree. Moreover, the idea of (proportionate) intervention with the aim of protecting health and perhaps life, is more compelling (or, at least, less controversial) than is the idea of intervention with the aim of affecting more value-laden life-style choices. Having said that, the fact that the benefit of fluoridation is capable of being conferred in another less intrusive way, points to an alternative approach. That would be to place a very strong emphasis on the role of education. Educating citizens as to the importance of dental hygiene and a good diet, while paternalistic to some extent, satisfies the Kantian ideal that 'what made men free was not acting in certain self improving ways, which they could be coerced to do, but *knowing that they ought to do so*, which nobody could do for, or on behalf, of anyone else'. An increased educational role then, *if it worked*, would be consistent with both a libertarian and a welfare liberal approach.

A problem with the above approach seems to lie in the proviso 'if it worked'. That is to say, it is unclear as to *how effective* respect for the Kantian ideal is likely to be with regard to, say, a six-year-old chocoholic who doesn't like cleaning her teeth. It is all very well to emphasise the value of autonomy, but the desire to *effectively* safeguard the health and safety of children (who are not yet autonomous) could be said to constitute a strong counter-emphasis.

Obviously, scientific evidence is vital to the issue of fluoridation. For simplicity, I have assumed that fluoridation is solely beneficial and looked at the moral tensions that remain. Any evidence to the contrary will, of course, weaken the arguments in favour of it, although perhaps not fatally. Even given a modicum of risk, we might still ask whether it could ever be ethical to withhold an on balance beneficial treatment, to fail to prevent suffering when it is within our power? To do so would be to deliberately fail to protect and promote the health of people in our community.

If we do not want to do that, fluoridation is undoubtedly an option *at the moment*. However, there would seem to be no reason as to why other options such as education, increased choices and 'structural redress' might together provide an alternative form of health promotion that is more harmonious with other deeply held values in society.'





Chapter 14

The Programme of
Oral Health Research
in Ireland

14 The Programme of Oral Health Research in Ireland

Background

Research in oral health has been carried out in Ireland since the middle of the last century. The programme of research currently being performed on behalf of the health boards, by both University College, Cork and Trinity College, Dublin, is discussed below. Review of this research is one of the terms of reference of the Forum.

Research on the role of fluorides in University College, Cork

Special Studies on Dental Caries and Fluorides

Following the introduction of water fluoridation in the early 1960s the Department of Health in Ireland established a research unit in University College Cork in 1966 entitled 'Special Studies on Dental Caries and Fluorides' designed to monitor the effectiveness of water fluoridation in Ireland. Over the subsequent 10 years this group reported on a number of studies including the Mallow, Macroom and Mitchelstown Study and also on the Cork City Study.^{57, 132}

National Survey of Children's Dental Health, 1984

In 1983 the Department of Health sponsored a national survey of children's dental health to be conducted by the Oral Health Services Research Centre in Cork. The field-work for the study was conducted in 1984 and was published by the Stationery Office in Ireland in 1986 and later in international journals.¹⁷

The results showed that life-time residents of fluoridated communities had considerably lower levels of dental decay than life-time residents of non-fluoridated communities. When account was taken of all the confounding variables using regression analysis it was found that water fluoridation was a significant factor in the lower levels found in fluoridated communities. The 1984 national survey in Ireland included a detailed measurement of the levels of enamel opacities including fluorosis. The results showed a slight but non-significant higher level of enamel fluorosis in life-time residents of fluoridated communities.

National Survey of Adult's Oral Health 1989-1990

In 1989/1990 the Health Research Board in Ireland and the EU in collaboration with the Department of Health sponsored the first national survey of adult dental health in Ireland.⁴ The study was conducted by the Oral Health Services Research Centre in UCC. Using regression analysis to take account of confounding factors the results showed that adults residing in communities served with fluoridated water had better dental health than residents of non-fluoridated communities.

Regional Surveys of Oral Health 1990-1999

Throughout the 1990s the different health boards monitored the effectiveness of water fluoridation by means of local studies conducted in collaboration with the Oral Health Services Research Centre in UCC. During this period 18,976 children were surveyed.¹³³⁻¹³⁹ All of these studies have shown that the levels of dental decay amongst children have continued to decline, the decline being greatest in life-time residents of fluoridated communities. The studies conducted in the 1990s also included the measurement of enamel opacities including fluorosis; the results showed that there has been an increase in prevalence in the 'questionable' and 'very mild' grades of enamel fluorosis in children in Ireland. These results have been published in the international literature.⁸¹ It is important to note that the terms 'questionable' and 'very mild' were the terms used by Dean and his co-workers in the 1940s to describe the low grade changes in enamel which they predicted would be likely to occur if the fluoride levels in water supplies were adjusted to one part per million.

Health Services Research Projects related to fluorides

The South Eastern Health Board initiated the first school-based fortnightly sodium fluoride mouth rinse programme in Ireland in 1967 in Waterford. The SEHB dental service and the Oral Health Services Research Centre (OHSRC) in University College Cork subsequently measured the effectiveness of this programme in preventing dental caries.^{25, 26} The retained impact of the programme on preventing dental caries amongst children who had stopped using the rinse on transition to secondary school was further evaluated 4 years following its cessation, again by the SEHB dental service in collaboration with the OHSRC, UCC.²⁷ In the mid-1990s a fortnightly fluoride mouth rinse programme was established and evaluated prospectively in Co Clare under the direction of the OHSRC.¹⁴⁰

In 1999 the Department of Health and Children commissioned a series of studies dealing with the impact of water fluoridation. The Oral Health Services Research Centre was contracted to carry out a number of projects that are currently in progress and these are described below.

National Survey of Adult Dental Health

The National Survey of Adult Oral Health is a joint venture between the Department of Health, the Health Boards and the Oral Health Services Research Centre, University College Cork. One of the main aims of this study is to measure the impact of water fluoridation on the oral health and quality of life of Irish adults. A random sample of adults in the 16-24, 35-44 and 65+ age groups are being examined for coronal and root caries. The youngest age group is also being examined for dental fluorosis. The study includes the following measures relevant to the impact of water fluoridation on oral and general health:

- Number of teeth
- Coronal and root caries levels
- Dental fluorosis
- Tooth wear
- Satisfaction with the colour of one's teeth
- Oral health related quality of life
- Subjects' history of exposure to domestic water fluoridation including fluoridation status of current and previous domestic water supplies
- Participants' history of bone fracture
- Participants' general health status as measured according to the American Society of Anaesthesiologists.

The fieldwork, being conducted by 30 teams of trained and calibrated health board dentists and dental nurses, will be complete in February 2002. Preliminary results will be available in the Autumn of 2002.

National Survey of Children's Dental Health

The National Survey of Children's Oral Health is a joint venture between the Department of Health, the Health Boards and the Oral Health Services Research Centre, University College Cork. One of the principal aims of this study is to measure the impact of water fluoridation on the oral health of Irish children. The field-work for this study commenced in November 2001 and will be completed in early 2002. An estimated 18,000 children aged 5-, 8-, 12- and 15-years-olds are to be examined in schools in the first survey of children's oral health to encompass both the Republic and Northern Ireland. The survey results will indicate trends in treatment patterns in the two jurisdictions and also measure the effectiveness of water fluoridation. The water supplies of Northern Ireland are not fluoridated; hence this collaboration is very welcome since it will allow direct comparison of the dental health of children in Northern Ireland and the Republic of Ireland. Thirty-two dentists and dental nurses are carrying out the fieldwork in the Republic of Ireland and 5 teams in Northern Ireland. These teams have been trained and calibrated in standardised examination techniques. The conditions relevant to the impact of water fluoridation to be measured in this study include:

- Number of teeth
- Coronal caries levels
- Toothpaste usage pattern
- Age of commencement of brushing
- Age-related stage of tooth eruption
- Feeding practices in infancy for 8-year-old group
- Dental fluorosis
- Standardised photographic recording of appearance of anterior teeth
- Tooth wear
- Satisfaction with the colour of one's teeth
- Awareness of marks on the teeth
- Experience of dental pain
- Subjects' history of exposure to domestic water fluoridation including fluoridation status of current and previous domestic water supplies.

Preliminary results will be available in early Autumn 2002.

Monitoring the use of fluoride modalities

The Oral Health Services Research Centre in UCC has undertaken to advise and assist the health boards in monitoring the use of various fluoride modalities in the prevention of dental caries including: fluoride mouth rinsing programmes, the use of fluoride gels, varnishes and fluoride toothpastes, other forms of systemic fluoride supplementation and combinations of fluoride modalities (including matters relating to intake). This research project includes a situation analysis which examines all fluoride programmes with regard to structure, process and outcomes with a view to determining best practice methodologies for the future monitoring and promotion of programmes by health board staff. As part of this project the Fluoride Laboratory in UCC is determining the fluoride content of foods and drinks and of toothpaste. Methods are also being developed for measuring the total dietary fluoride intake by 2-3 year old children and baseline information on current levels of fluoride absorption in Irish children is being measured using fingernail clippings. These studies are being undertaken in close collaboration with colleagues in Europe and the US in order to make sure that the methods being used conform to international standards. The final report for this project is due in December 2002.

Other Studies Related to Fluoride in the OHSRC

The research programme being carried out on behalf of the health boards is part of a wider research programme on oral health being conducted by the dental schools in Ireland. It includes some fluoride research supported by agencies other than the health boards. For example, the use of fingernail clippings as biomarkers for monitoring fluoride intake is jointly funded by the Health Research Board and the Department of Health Research Contract.¹⁴¹ The development of a standardised photographic technique to measure dental

fluorosis¹⁴² and fluoride ingestion and absorption from toothpaste in 7 EU countries was funded by the EU 5th Framework Biomed 2 Programme.¹⁴³ The final report of this project has been submitted to the EU. The results of this project will be submitted for publication to Community Dentistry and Oral Epidemiology in April 2002.

An Evaluation of Water Fluoridation Systems in Ireland, by Trinity College, Dublin

The aim of this project was to carry out an evaluation of quality and performance of the fluoridation of public water supplies with regard to structure, process and outcomes, in order to determine best practice methodologies appropriate to all aspects of water fluoridation.

This evaluation comprised the collection of information on a number of aspects of the technical processes involved in the fluoridation of public water supplies. These included the results of monthly monitoring of fluoride levels in drinking water, the local management of water fluoridation, followed by a detailed analysis of a number of water treatment plants. A draft report and recommendations are being prepared which will be disseminated following consultation with the Department of Health and Children, the Department of the Environment and Local Government, the health boards and local authorities.

The recommendations will address three key areas:

- Collection and reporting of results data
- Data to be collected and reported
- Format and frequency of reports
- Identifiers for water supplies

- Inter-agency management of the water fluoridation process
- Fluoridation monitoring committees
- Roles of key personnel

- Operational issues in water treatment plants
- Information manual for plant personnel
- Quality assurance programmes
- Health and safety audits
- Training issues.

The Department of Public and Child Dental Health at TCD has been involved in two recent studies investigating fluorosis levels in children in Dublin, and a further fluorosis study is planned. Another study being planned will investigate some of the issues relevant to the water fluoridation process.

Other Relevant Research

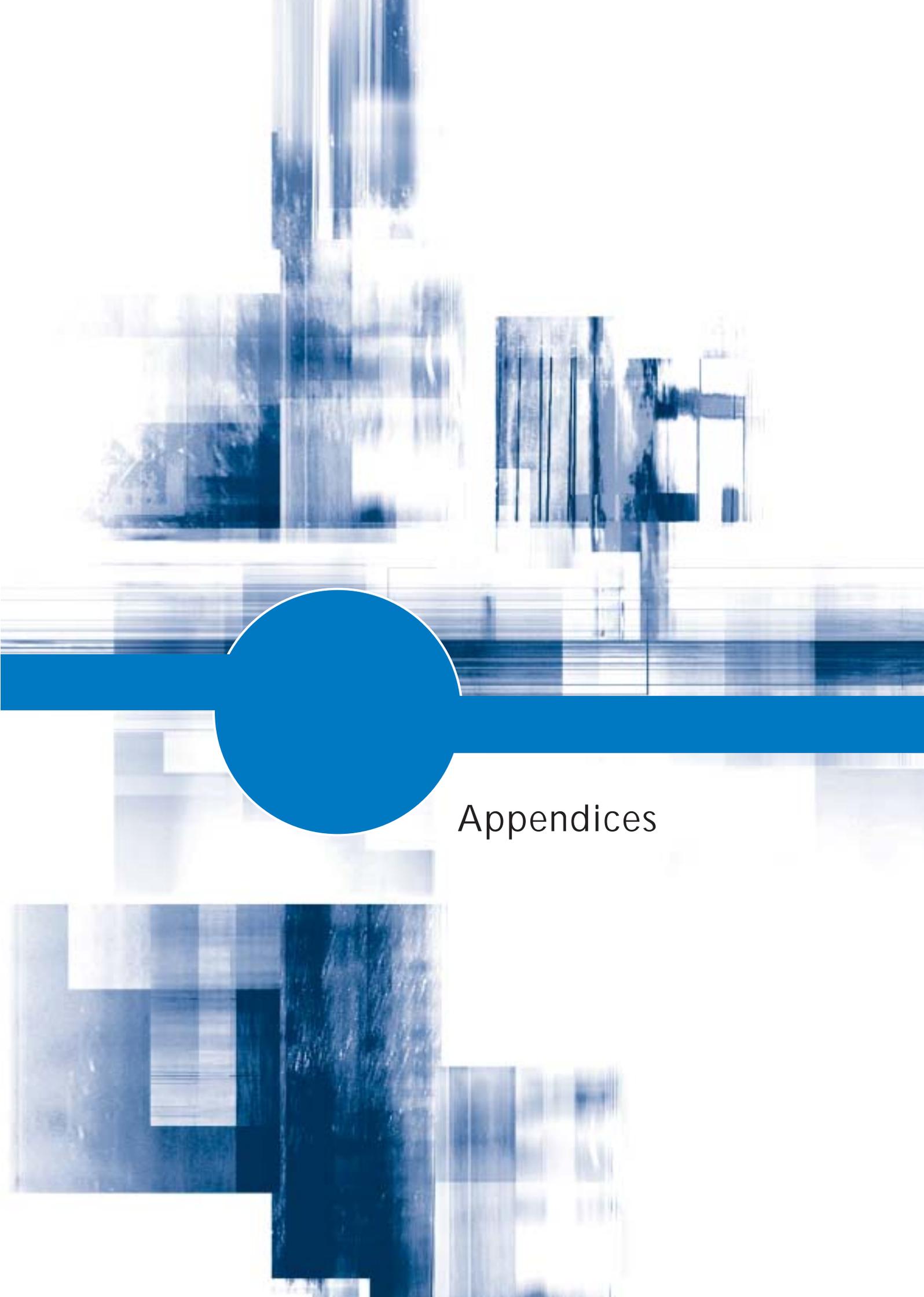
A review of the risks of overdosing/underdosing of fluoride in public drinking water supplies in the South Eastern Health Board was undertaken by an environmental health officer and was presented to the Forum in February 2001.

The main recommendation of this review is that an Irish code of practice for water fluoridation plants should be developed in consultation with the relevant government departments, local authorities, health boards, the Health and Safety Authority, equipment and chemical supplies. Such a code should cover all aspects of water fluoridation systems, from operational issues to design. This code would likely be very similar to the UK Department of Environment, Transport and the Regions 1987 Code of Practice on technical aspects of fluoridation of water supplies or the US MMWR 44 (RR-13) 1995 Engineering and Administrative Recommendations for Water Fluoridation.^{144, 145}

This code would address issues under the following headings:

- Source protection and monitoring
- Hydrofluorosilicic acid delivery and storage
- Day tank
- Dosing
- Plant pipework
- On site dose monitoring
- Training
- Plant security





Appendices

Public Consultation Methodology

One of several Forum Sub-Groups was established to co-ordinate, analyse and assess the responses to the distribution of the comment form, which formed the principal element in the task of Public Consultation with which the Forum was charged. Because of the very diverse nature of the responses to the consultation (comprising the comment forms, with or without accompanying pages or references, e-mails and letters sent independently of the comment form, and a small number of petitions), it was considered appropriate, as explained below, to use e-mail communication of material and views between members over a period of some five weeks, and accompanied by one meeting, at which the programme of the Sub-Group was finalised. Likewise, the finalisation of the Sub-Group report was carried out via e-mail.

The only public submissions to the Forum which were not dealt with by the current Sub-Group were those from professional and public bodies and from non-governmental organisations. Of their nature, such submissions required a higher degree of specific specialist expertise in their assessment, and were accordingly referred to the appropriate specialist members of the Forum.

In brief, the approach adopted was as follows. The convenor of the Sub-Group mentioned and the Secretary to the Forum, working in collaboration, checked that each response received bore an accession number; while the forms issued were numbered serially, numbers were allocated on receipt to e-mails, letters etc. A computerised data base was then set up, with an array of fields corresponding to the seven numbered sections of the comment form, but with many additional fields covering specific points (e.g. perceived specific ill-effects of fluoridation) raised by respondents. Each response received was entered in the data base and was duly taken into consideration by the members of the Sub-Group. The only exceptions to this approach arose where literally a few members of the public had spontaneously sent a written submission and subsequently returned a comment form which had been sent to them as a matter of course. In these instances, the combination of letter and comment was regarded on grounds of equity as a single submission.

The use of the data base approach to the analysis of the comments elements of the responses also proved convenient. It had been clear from the outset that the task of the reading of each response by the five individual Sub-Group members might not prove practicable. Quite apart from the logistics of circulating and sorting over 1,000 pieces of mail to five addresses in turn, the total time demand rendered this procedure impossible. Instead, the individual scrutiny of the responses was undertaken by the convenor of the Sub-Group who, concurrently and using a lengthy list of 'standard' abbreviations devised by him, entered in condensed (but not 'edited', in the sense that any intended meanings were altered) form the views of respondents in two wide data fields corresponding to Sections 5 and 7 of the Comment Form. (The Comment Form is presented in Appendix 2.) The

completion of this task by a single person made for a satisfactory degree of consistency of approach.

On completion of the data base entries, copies of it and the abbreviations list were circulated by e-mail to all members of the Sub-Group, who were then more conveniently able to make a preliminary assessment of the responses. When the Sub-Group subsequently met, it had available the complete, catalogued and sorted responses to the Consultation. An independent scrutiny of the original submissions was then made, separately, by two members of the Sub-Group. As the database included the response accession numbers, the making of specific and random checks of the veracity of the database was straightforward. One member of the Sub-Group carried out a random check on the submissions, while another scrutinised each reply in detail. On completion of this latter task any errors made in the initial assessment were rectified.

The creation of the database had other benefits besides facilitating cross-checking of entries with original responses. It made it simple to ensure that each response was logged, recorded and taken into account. The fear had been expressed in a few replies that the public consultation exercise would be merely a matter of form, and that scant attention might be paid to responses. The Forum can assure all respondents that this is emphatically not the case and that all responses from the public were given due attention.

**THE FORUM ON
FLUORIDATION**

**Appointed by Mr. Micheal Martin TD
Minister for Health and Children, 2000**

***Seeking the Views of Consumers
on the Fluoridation of Public
Water Supplies***

A very important task given to the Forum by the Minister is the matter of public consultation. It is essential to the work of the Forum that the views of the public at large, who are the consumers of public water supplies, on any or all aspects of the fluoridation of drinking water should be ascertained and taken into account in the preparation of the Final Report of the Forum which is due for submission to the Minister in September 2001.

This public consultation will take place in different ways and there is an open invitation to members of the public to submit their views to the Forum in such manner as they may wish. However, the Forum realises that some consumers may neither have the time nor wish to make a submission with any degree of formality, perhaps because they feel they are not qualified or they lack the information to do so. The Forum is anxious to stress that **all** views of consumers are both welcome and of value, and has devised the

present form to enable consumers to express such views in an informal and straightforward manner.

*Please read the notes overleaf before entering
your comments in this form*



MY COMMENTS ARE AS FOLLOWS:

1. I approve/do not approve¹ of the fluoridation of drinking water supplies.
2. I would approve/not approve of an alternative method of providing fluoride to the public.
3. I consider the benefits of fluoridation to be as follows:

.....

.....

.....

.....

.....

4. I consider the ill-effects of fluoridation to be as follows:

.....

.....

.....

5. My concerns/views about the addition of fluoride to drinking water are:

.....

.....

.....

.....

.....

(Continued overleaf)

¹ Please delete as appropriate under all headings.

Public Consultation: Geographical Scope

The following table lists the towns or general area from which the submissions originated. While the geographical coverage is not uniform, many of the locations are widely dispersed and indicate that interest in the consultation and its subject was not the preserve of any given area. The geographical designations used are almost invariably those used in the submitted forms. The figures in brackets following each location name are the numbers of responses received from that location. (A total of ten responses did not bear any geographical indication.)

Location/Responses	Location/Responses	Location/Responses
Adamstown (1)	Bantry (7)	Castlegar (1)
Adare (1)	Barna (1)	Castleisland (1)
Annacotty (1)	Barndarrig (1)	Castleknock (2)
Annascaul (1)	Belmullet (1)	Castlepollard (2)
Ardara (1)	Bettystown (1)	Castlerea (2)
Ashford (1)	Binghamstown (1)	Castletownbere (5)
Askeaton (1)	Blacklion (1)	Celbridge (2)
Athboy (1)	Blackrock (C) (1)	Clarecastle (1)
Athlone (4)	Blackrock (D) (9)	Clonakilty (2)
	Bodyke (2)	Clondalkin (1)
Bagenalstown (1)	Boosterstown (4)	Clondra (2)
Balbriggan (3)	Boyle (2)	Clonee (2)
Ballaghaderreen (1)	Bray (7)	Clonegal (2)
Ballinaglera (1)	Bunclody (1)	Clones (2)
Ballinamult (2)	Buncrana (2)	Clonmany (2)
Ballinasloe (1)	Burt (1)	Clonmel (1)
Ballingeary (1)	Burtonport (1)	Clontibret (1)
Ballybofey (1)		Co Carlow (1)
Ballycumber (1)	Cabinteely (1)	Co Clare (18)
Ballydehob (1)	Caherciveen (1)	Co Cork (4)
Ballyferriter (1)	Callan (1)	Co Donegal (3)
Ballyhaunis (1)	Calry (1)	Co Dublin (N) (1)
Ballyjamesduff (1)	Carlow (2)	Co Dublin (S) (1)
Ballymote (1)	Carndonagh (1)	Co Galway (7)
Ballymurray (1)	Carney (1)	Co Kerry (3)
Ballyshannon (2)	Carrickmacross (1)	Co Kildare (1)
Ballysimon (1)	Carr-on-Shannon (1)	Co Kilkenny (4)
Ballysodare (2)	Carrigaline (4)	Co Laois (1)
Ballyvaughan (2)	Carrigtwohill (1)	Co Leitrim (2)
Baltimore (1)	Cashel (1)	Co Limerick (1)
Baltinglass (1)	Castlebar (1)	Co Longford (1)
Bandon (3)	Castleconnell (1)	Co Mayo (1)

Location/Responses		Location/Responses		Location/Responses	
Co Meath	(5)	Dublin 12	(16)	Hollywood (W)	(1)
Co Roscommon	(1)	Dublin 13	(8)	Howth	(3)
Co Sligo	(5)	Dublin 14	(20)		
Co Waterford	(2)	Dublin 15	(4)	Inishmore	(1)
Co Wexford	(1)	Dublin 16	(14)	Innishannon	(2)
Co Wicklow	(4)	Dublin 18	(14)	Inver	(3)
Coachford	(1)	Dublin 22	(1)		
Cobh	(3)	Dublin 24	(7)	Kenmare	(1)
Collon	(1)	Dublin 26	(1)	Kilbeggan	(1)
Collooney	(2)	Duleek	(1)	Kilcoole	(1)
Connemara	(1)	Dun Laoghaire	(10)	Kilcullen	(2)
Cork	(40)	Dunboyne	(12)	Kilkenny	(15)
Cork City	(5)	Dundalk	(2)	Killala	(7)
Courtmacsherry	(1)	Dundrum (Tipp)	(1)	Killaloe	(2)
Craughwell	(1)	Dungarvan	(2)	Killarney	(4)
Creeslough	(1)	Dunshaughlin	(6)	Killiney	(6)
Crosshaven	(3)			Killorglin	(1)
Crossmolina	(1)	East Donegal	(1)	Killybegs	(1)
Curracloe	(2)	Edenderry	(1)	Killygordon	(1)
		Ennis	(2)	Kilmacanogue	(1)
Dalkey	(6)	Enniscorthy	(1)	Kilmacow	(1)
Deansgrange	(1)	Enniskerry	(1)	Kilmacud	(3)
Derry	(1)	Ennistymon	(2)	Kilmaine	(1)
Donabate	(1)			Kilmallock	(1)
Donard	(3)	Falcarragh	(2)	Kilrane	(1)
Donegal Town	(2)	Feakle	(2)	Kilrush	(1)
Donoughmore	(1)	Fedamore	(1)	Kilsallaghan	(1)
Doolin	(2)	Fenit	(1)	Kingscourt	(2)
Drogheda	(1)	Finglas	(1)	Kinvara	(1)
Drumahaire	(1)	Fountainstown	(3)		
Drumcollogher	(4)	Foxford	(3)	Lahinch	(4)
Drumfin	(1)	Frosses	(5)	Leitrim/Cavan	(1)
Drumshanbo	(1)			Leixlip	(1)
Dublin	(14)	Galway	(24)	Letterfrack	(1)
Dublin 2	(1)	Galway City	(7)	Letterkenny	(4)
Dublin 3	(13)	Garristown	(1)	Limerick	(5)
Dublin 4	(14)	Geashill	(2)	Limerick City	(2)
Dublin 5	(10)	Glenageary	(2)	Lisnaskea	(2)
Dublin 6	(15)	Glounthaune	(1)	Longford	(3)
Dublin 6W	(16)	Gorey	(2)	Loughrea	(2)
Dublin 7	(20)	Gortahork	(1)	Lucan	(8)
Dublin 8	(11)	Greystones	(5)	Lusk	(2)
Dublin 9	(52)				
Dublin 11	(14)				

Appendix 3 Public Consultation: Geographical Scope

Location/Responses		Location/Responses	
Macroom	(4)	Sallins	(1)
Malahide	(4)	Sandycove	(1)
Midleton	(2)	Scarriff	(1)
Milltown (D)	(1)	Schull	(2)
Miltown Malbay	(1)	Shankill	(4)
Monasteraden	(1)	Shannon	(2)
Monkstown (C)	(1)	Shillelagh	(1)
Monkstown (D)	(8)	Skerries	(7)
Mount Merrion	(6)	Sligo	(12)
Mountshannon	(2)	Sligo Town	(10)
Moville	(1)	South Dublin	(2)
Mullingar	(9)	South Kilkenny	(1)
Mulrany	(1)	St Margaret's	(2)
		Stamullen	(1)
Naas	(4)	Stillorgan	(14)
Navan	(11)	Strandhill	(1)
New Ross	(2)	Stranorlar	(3)
Newbridge	(1)	Swinford	(1)
Newport (Tipp)	(2)	Swords	(5)
North Clare	(1)		
North Dublin	(1)	Taghmon	(1)
North West	(1)	Thurles	(1)
		Tipperary	(1)
O'Callaghansmills	(2)	Tipperary NR	(1)
Ogonnelloe	(2)	Tipperary South	(1)
Oola	(1)	Tralee	(11)
Oranmore	(2)	Tramore	(3)
Oughterard	(1)	Trim	(1)
Ovens	(1)	Tuam	(1)
		Tubbercurry	(1)
Phibsborough	(1)	Tulla	(1)
Portmarnock	(1)	Tullamore	(3)
Portrane	(1)		
Portsalon	(2)	Waterfd/Kkenny	(1)
		Waterford	(8)
Ramelton	(1)	Waterford City	(2)
Rathcormac	(1)	Westmeath	(1)
Rathdrum	(1)	Westport	(6)
Ratoath	(2)	Wexford	(5)
Riverstn (Sligo)	(2)	Wicklow Town	(3)
Rosscarbery	(1)		
Rush	(1)	Youghal	(2)
Rylane	(1)		

Detailed Findings of the Consultation

(See Appendix 2 for details of the Comment Form)

1. I approve/ do not approve of the fluoridation of drinking water supplies.

Response	No. of Replies	Percentage
Approve	90	8.60
Disapprove	931	89.01
No view	25	2.39
TOTAL	1,046	100

The respective percentages for Disapprove and Approve based on the number of positive responses (90 + 931 = 1021) are: 8.81 and 91.19.

2. I would approve/ not approve of an alternative method of providing fluoride to the public

Response	No. Replies	Percentage
Approve/ No Comment	234	22.37
Approve/ With Comment	71	6.79
Disapprove/ No Comment	503	49.09
Disapprove/ With Comment	25	2.39
No View/ No Comment	208	19.88
No View/ With Comment	5	0.48
TOTAL	1,046	100.00

Forty comments indicated that the approval given was conditional on a choice being given, and fifty-four comments indicated that approval would be given if consumers had a choice.

3. I consider the benefits of fluoridation to be as follows

Response	Percentage Replies
No Comment	23.0
Positive comment on benefits	31.0
Negative comment on benefits	45.0
Inapplicable comment	1.0
TOTAL	100.0

Note that percentages are approximate (and hence indicative only) because of the inherently variable nature of individual comments.

4. I consider the ill-effects of fluoridation to be as follows

Response	No. Replies	Percentage	
Replies with comment	893	85.37	
Replies without comment	153	14.63	
Alzheimers	5%	Dental fluorosis	30%
Arthritis	3%	Enzyme Inhibition	3%
Cancers (All)	34 %	Hip fractures	6%
Immune system	4%	Irritable Bowel syndrome	14%
Osteoporosis	28%	Reduced IQ	5%
Skeletal fluorosis	6.5%	Thyroid problems	8%

The comments refer in the main to perceived actual/possible/potential conditions attributable to fluoridation of drinking water supplies. Again, because of the nature of such comments a precise analysis of replies is virtually impossible, but the numbers of references to specific conditions are indicative. Note that many comments made reference to more than one illness.

5. My concerns/views about the addition of fluoride to drinking water are:

See under Section 7 below.

6. I/my family/my children regularly use toothpaste containing fluoride **Yes / No**

Response	No. of Replies
Yes	464
No	427
Usage not indicated	155
TOTAL	1,046

Note that there were many qualifying comments under this heading. A great number of these referred to the difficulty of access to non-fluoridated toothpaste, and many implied that were the latter available the responses would have been different. For this reason, no percentage figures have been calculated, and a precise outcome cannot be arrived at.

7. I have the following additional remarks to make to the Forum:

The responses under these headings 5 and 7 were combined for analysis because of the overlapping manner in which many responses were presented; however, there is little difference between the two, the one being complementary to the other. Each individual submission was examined and the points raised or themes arising from it noted.

As with earlier headings, because of the nature of such comments a precise analysis of replies is virtually impossible, but the following ranking of themes and topics reflects as closely as practicable the views expressed by respondents. It is important to note that two or more of the issues below may be reflected in a single comment.

Principal issue/theme arising from survey submissions	Note
1. Concern over perceived or possible ill-effects on health of people/nation	Note 1
1. Consumers'/citizens' lack of choice in the matter of ingesting fluoride	Note 1
2. Opposition to perceived enforced mass medication of population	
3. View that fluoridation is unnecessary per se, or because of alternatives	Note 2
3. Banning/non-use of fluoride in other European countries in contrast to here	Note 3

Appendix 4 Detailed Findings of the Consultation

4. Criticism of breaches of rights/unethical-immoral-illegal act of fluoridation	Note 4
4. View that access to natural potable water is a human right which is violated	Note 5
5. Adverse reaction to exposure of population to perceived toxic additive	
5. Positive expressions that fluoridation should be halted	Note 6
6. View that personal intake of fluoride is effectively uncontrollable in reality	Note 7
7. Failure of Government to carry out health effects study (as per 1960 Act)	
7. Fluoride used is Waste Product of Fertiliser Industry	
8. Dissatisfaction with Government in various fluoridation-related matters	Note 8
8. Comments approving of and/or advocating continuation of fluoridation	Note 9
9. General concerns about the lack of information for the public on fluoride	Note 10
10. Expression of objection to fluoridation without consent of the population	Note 6
11. Concern over financial/other hardship which limits/rules out bottled water	Note 11
11. Concerns/doubts over fluoride dosing techniques by sanitary authorities	Note 12
11. Concern over reported contaminants of fluoride used: arsenic, lead etc	
11. Concerns and worries over possible long-term ill-effects of fluoride	Note 13
11. View that if ill-effects are proven there will be consequential litigation	Note 14
11. Concern re possible overdosing due to F in water and food and toothpaste	
12. Statement that there are no proven benefits of fluoridation	Note 6
12. Expression of need for and concern over possible lack of careful monitoring	Note 15
12. Perceived need to use water filters; inapplicability of most to fluoride	Note 16
12. Specific concern of excess F dose to infants with feed made up with FDW	Note 17
12. Concern regarding the difficulty for some of avoiding the use of FDW	Note 18
12. Concerns of varying gravity about the large F discharges to environment	Note 19

NOTES

(F)DW denotes (fluoridated) drinking water; F: Fluoride; FTP: Fluoride-containing toothpaste

1. As was perhaps to be expected these themes dominated the responses more or less equally.
2. The term 'unnecessary' covers views expressed (a) that addition of F to DW is no longer necessary because of improved hygiene, (b) that FTP is a readily available alternative, (c) that other sources of F exist widely, etc.
3. Topic includes the often asked question why IRL persists with F, the advice to 'follow Europe' etc.
4. Many trenchant views were expressed as to the unconstitutionality/illegality/criminality/madness etc of mass fluoridation, and on the undemocratic and unethical nature of the process. In addition there were many references to breaches of civil and/or human rights. All such are included here.
5. Many concerns about DW are included here – the addition of chemicals, tampering with a natural resource to which there is a human right, the undesirable precedent set by the addition of a non-essential substance to DW.
6. This ranking is indicative only, as the themes have been covered in responses to earlier sections.
7. There is a widely-held view that a person's F dose (as quite distinct from the dosage of F by the local authority) is uncontrolled and unknowable, considering the multiplicity of natural F sources (tea, fish etc). The consequences of this position are feared by many and there is great concern about the voluntary (or in some cases medically recommended) acceptance of the advice that up to 3 litres of water a day should be ingested, which might lead to an effective overdose of F.
8. There is criticism of the State, the Government, the Minister and the Department. The tenor of this varies considerably, but there are some strongly-held views.
9. All approbatory comments and requests that fluoridation be continued are included here.
10. There is a discrete sector of the respondents who wish to have complete information (both pro and anti) on fluoridation and who look to the Forum to meet this requirement. Recommendations for greater education are included here.
11. Although few in number, there are transparently honest concerns about the financial burden or impossibility on grounds of expense of obtaining bottled water in order to avoid the enforced ingestion of fluoride by using the public water supply. In other cases, respondents feel it necessary to travel considerable distances to obtain fluoride-free DW.

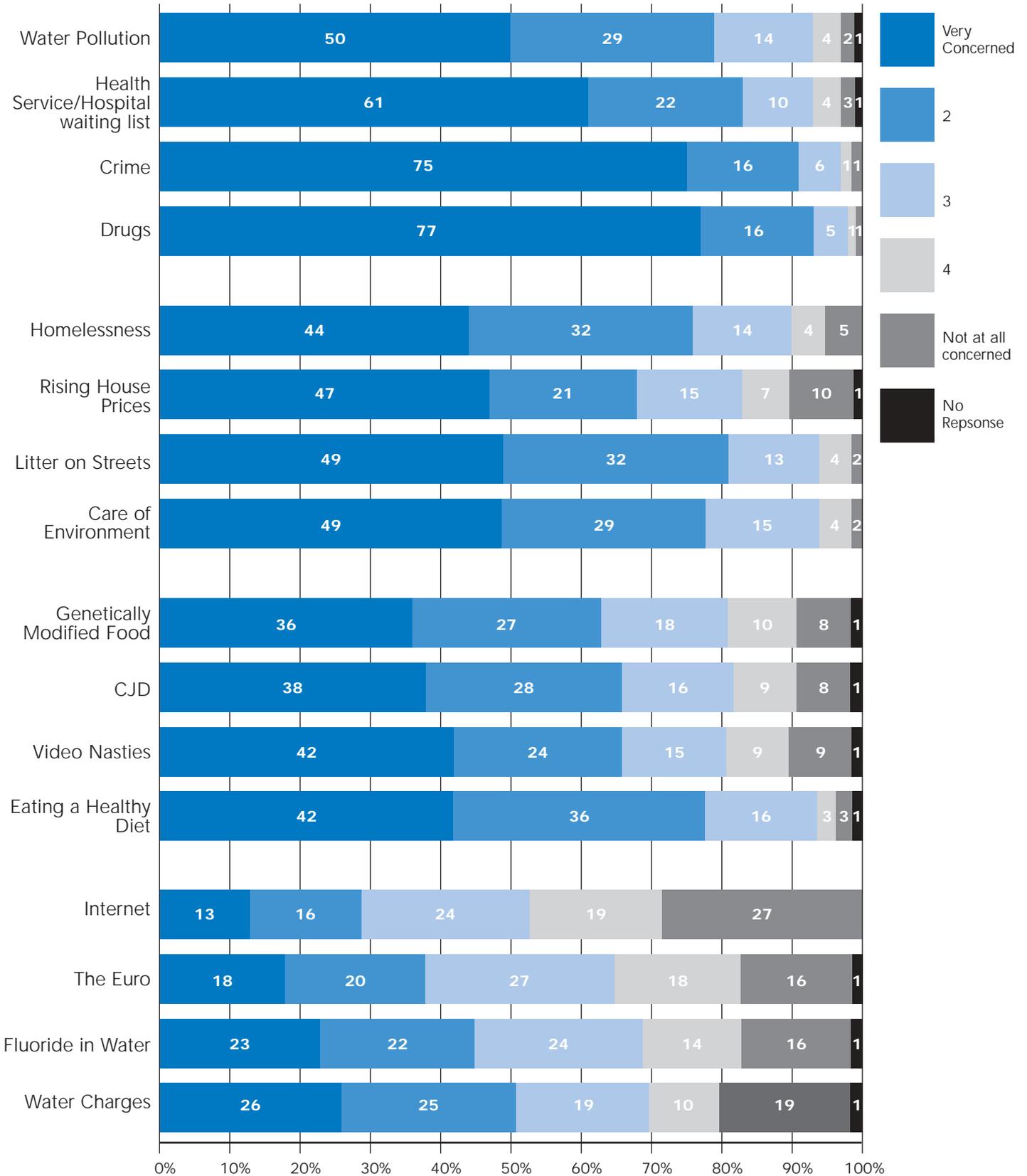
12. Again few in number, some of the points made are very relevant.
13. The figure probably under-reflects the great concern over long-term effects, as yet unknown, on both the individual's and the nation's health.
14. Although the respondents' perspectives may vary, there are some cogent statements about the possibility of wide-scale legal action should ill-effects of F be proven.
15. Some of the points made in regard to monitoring are very pertinent.
16. Some respondents have felt constrained to install one or more filters to rectify problems with their DW, but others point out correctly that no domestic-level filter will in fact remove fluoride.
17. Although few, these views reflect a genuine concern in regard to infant's feed being prepared with FDW. Some responses state that there is no dose/body weight relationship for F and that babies and adults are treated as equivalent.
18. Unavoidability of ingesting F in DW is referred to specifically in some responses. (cf Notes 11/16).
19. While it is true that virtually all fluoridated water reaches the aquatic environment, through legitimate non-ingestive uses, the fears expressed do not seem valid (cf Appendix 10).

The principal themes arising from the comments submitted to the Forum number about 30, and they are shown in the above Table in decreasing order of frequency. For convenience, where appropriate, the themes have been grouped (e.g. as 'joint third' etc). It must be stressed that the ranking in order of frequency does not have any implications for the importance of any theme. Wherever possible, each topic raised by the public has been addressed by the Forum at the appropriate point in the Forum Report.

The fact that perhaps only a few respondents adverted to a given topic is not taken by the Forum to imply that such theme is inconsequential. Once a topic has been raised, it is relevant and hence no attempt has been made to 'weight' the themes in order of apparent importance or significance.

Dental Health Foundation Commissioned Research

For each of the following issues I read out please tell me your level of concern, on a scale of 1 to 5



Views of Individual Local Authorities, Health Boards and Professional Bodies

A number of submissions were received from professional bodies/organisations, local authorities and health boards. These submissions were reviewed by members of the Forum and the views expressed are summarised below.

1. Midland Health Board

Broad overview of fluoridation in Ireland: areas discussed included: improved oral health in fluoridated areas versus non-fluoridated areas, and alternatives to fluoridation such as salt, oral hygiene, sugar reduction, fissure sealants. Concluded that water fluoridation is effective. Reviewed safety – concluded no adverse effects.

Conclusion: Strong support for water fluoridation.

2. Naas Urban District Council

Two major issues:

- External/topical application is the best of delivery
- Not possible to accurately devise a 'national dose'

Conclusion: List of 13 questions outlined to the Forum - many of a general nature.

3. Southern Health Board

Conclusion: Proposal to monitor caries levels in Ireland using a system developed by the British Association for the Study of Community Dentistry.

4. North Western Health Board

Summary statement by Chief Executive Officer addressing key issues and supporting water fluoridation. A report on dental decay in NWHB was presented illustrating differences in dental health on either side of the border with Northern Ireland. Caries levels, dental fluorosis and levels of fluoride in the water were employed to illustrate this point, cross-border comparisons; dental fluorosis levels; fluoride levels; monitoring and other issues.

Conclusion: Support water fluoridation.

5. Foyle Basin: a Local Authority

A three item proposal:

- Stop fluoridation
- Start independent studies on health effects
- Right to choose fluoride free water

6. Western Health Board

An overview of effect of fluoride was presented, which addresses health risks and outlines some issues to be addressed.

Conclusion: support water fluoridation, safety, need for further research.

7. Galway Community Services

A review of the role of the Fluoridation Committee in WHB was presented.

Recommendations were made to Forum on:

- Management of fluoridation
- Manpower/training of staff
- Testing of water
- Epidemiological needs

Makes general comments for future.

Conclusion: Supports water fluoridation.

8. Dublin Dental School

Conclusion: Statement of support for water fluoridation.

9. Mid Western Health Board

- Review/statement by Director of Public Health: supports fluoridation but outlines need for better research.
- Principal Dental Surgeon: Reviewed current status of oral health in region; supports water fluoridation; points to dental fluorosis as only 'side effect' and shows low prevalence in MWHB.

Conclusion: Supports fluoridation and further research.

10. Killarney UDC

Motion to stop fluoridation - no supporting evidence.

11. Irish Women's Environmental Network

Conclusion: Outlines 6 points which are negative to water fluoridation.

12. Irish Dental Association

Reviewed water fluoridation; evidence for efficacy internationally and in Ireland; safety; dental fluorosis; future research strategies.

Conclusion: Supports fluoridation and need for continuous monitoring.

13. Society of Chief and Principal Dental Surgeons

Conclusion: Statement supporting water fluoridation.

14. Dental Health Foundation

Conclusion: Statement of support for water fluoridation.

15. Health Research Board

Outlines opportunities for research.

Copy of recent report on International Collaborative Research Report on research needs was provided.

The Fluoridation Act, 1960, and Specimen Regulations, 1965

Number 46 of 1960

HEALTH (FLUORIDATION OF WATER SUPPLIES) ACT, 1960.

AN ACT TO PROVIDE FOR THE MAKING BY HEALTH AUTHORITIES OF ARRANGEMENTS FOR THE FLUORIDATION OF WATER SUPPLIED TO THE PUBLIC BY SANITARY AUTHORITIES THROUGH PIPES AND TO PROVIDE FOR CERTAIN OTHER MATTERS CONNECTED WITH THE MATTER AFORESAID.
{28th December, 1960.}

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

Definitions

1.- In this Act-

"fluoridation" includes the addition of fluorine in any form;

"health authority" has the meaning assigned to it by virtue of the Health Act, 1947, and the Health Authorities Act, 1960;

"the Minister" means the Minister for Health;

"sanitary authority" has the same meaning as in the Local Government (Sanitary Services) Acts, 1878 to 1952.

Arrangement by health authorities for the fluoridation of water

2.- (1) Subject to and in accordance with this Act and regulations made under subsection (3) of this section, a health authority shall arrange for the fluoridation of water supplied to the public by sanitary authorities through pipes.

(2) The Minister may, in relation to a particular health authority, fix a date before which they shall, in relation to a particular public water supply, arrange for the fluoridation of water derived therefrom.

(3) (a) The Minister may make regulations as to the manner in which and the extent to which health authorities shall perform their functions under this Act, and such regulations shall in particular provide for the specification of the amount of fluorine (which shall not exceed one part by weight of fluorine per million parts of water) which may be added to a water supply.

(b) Regulations made under this subsection may relate to one or more health authorities and different regulations may be made in relation to different health authorities.

(4) Before making regulations under this section, the Minister shall-

(a) cause to be made-

(i) a survey of the incidence of dental caries in a representative sample of pupils attending full-time day schools in the functional area or functional areas of the health authority or health authorities to whom the regulations relate, and

- (ii) an analysis or series of analyses of the quantities of fluorine and such other constituents as the Minister may determine in the water supplied by sanitary authorities through pipes to the public in the functional area or functional areas of the health authority or health authorities to whom the regulations relate, and
- (b) cause to be presented to each House of the Oireachtas a report on the survey and analysis or analyses so made, and such report, in relation to the survey, shall include particulars of the procedure adopted in making it and the numbers, classified by age and otherwise, of the pupils to whom it relates but shall not include any information in respect of any identifiable pupil.

(5) Any information in relation to dental caries in individuals which is obtained in the course of a survey under subsection (4) of this section shall be treated in a confidential manner.

(6) Nothing in subsection (4) of this section shall be construed as imposing an obligation on any person to submit himself or any person for whom he is responsible to examination or as requiring the controlling authority of any school to afford facilities for the making of a survey under that subsection, and accordingly where, in the case of any such survey, information regarding the pupils attending one or more of the full-time day schools in the area or areas concerned is for any reason not available, the survey shall be made by reference to the pupils attending the other full-time day schools in the area or areas.

Appropriate health authority to arrange for fluoridation.

3.- (1) Where water from a particular public water supply is supplied to the functional area of one health authority only, the fluoridation of water derived therefrom shall be arranged by that health authority.

(2) Where water from a particular public water supply is supplied to the functional areas of two or more health authorities, the fluoridation of water derived therefrom shall be arranged by such of those health authorities as the Minister may determine.

Duties of sanitary authorities in relation to the fluoridation of water.

4.- (1) (a) The Minister may, after consultation with the Minister for Local Government, make regulations under this subsection requiring sanitary authorities to perform, as agents for health authorities, such acts, in relation to the fluoridation of water, as the Minister thinks fit and specifies in the regulations.

(b) Regulations under this subsection may relate to one or more sanitary authorities and different regulations may be made in relation to different sanitary authorities.

(c) Every sanitary authority shall, notwithstanding anything contained in the Local Government (Sanitary Services) Acts, 1878 to 1952, or in any local Act relating to the supply of water to the public, comply with any regulations made under this subsection which are applicable to that sanitary authority.

(d) A sanitary authority may, with the consent of the Minister for Local Government, borrow for the purpose of defraying any expenses incurred by them under

regulations made under this subsection as if they were expenses under the Local Government (Sanitary Services) Acts, 1878 to 1952.

(e) The appropriate health authority shall pay, on demand, to a sanitary authority any expenses (including payment of loan charges) incurred in a local financial year by that authority under regulations made under this subsection.

(2) Where the Minister has, under subsection (2) of section 2 of this Act, fixed in relation to a particular health authority, a date before which that health authority shall, in relation to a particular public water supply, arrange for the fluoridation of water derived therefrom, a sanitary authority who are required by regulations made under subsection (1) of this section to perform, as agent for that health authority, certain acts in relation to the fluoridation of water shall before that date perform those acts in relation to that particular public water supply.

Contribution by one health authority to another where water derived from a public water supply serves the functional areas of both authorities

5. (1) Where a health authority (in this section referred to as the arranging authority) arrange for the fluoridation of water derived from a public water supply which serves any part of the functional area of another health authority, that other health authority shall pay on demand to the arranging authority, in respect of the cost of the expenses (including payment of loan charges) incurred in a local financial year by the arranging authority in respect of such fluoridation, a sum bearing to the total expenses the same ratio (estimated as closely as is reasonably practical) as the amount of water supplied in that year to the functional area of that other health authority bears to the total amount of water supplied from that public water supply.

(2) If any dispute arises as to the amount of the payment to be made under subsection (1) of this section by one health authority to another health authority, the dispute shall be referred to and decided by the Minister.

(3) Notwithstanding the provisions of subsection (1) of this section, any two health authorities may make and carry out an agreement that neither of them shall make to the other any payment which would otherwise be proper to be made pursuant to that subsection.

General duty of the Minister as respects health surveys

6. (1) It shall be the duty of the Minister to arrange from time to time for such surveys as appear to him to be desirable to be made as respects the health, or any particular aspects of the health, of persons, or of particular classes of persons, in the functional area of a health authority in relation to whom regulations under section 2 of this Act are in force.

(2) A survey under this section may be arranged through the health authority or their officers or through such other organisation or body as the Minister considers appropriate.

(3) The Minister shall cause to be presented to each House of the Oireachtas a report on a survey made under this section but such report shall not include any information in respect of any identifiable person.

(4) Any information in relation to the health of individuals which is obtained in the course of a survey under this section shall be treated in a confidential manner.

(5) Nothing in this section shall be construed as imposing an obligation on any person to submit himself or any person for whom he is responsible to examination.

Duty of health authority to make estimate of incidence of dental caries in their functional area

7. (1) It shall be the duty of each health authority, whenever and so often as the Minister so requires, to make, before such date as the Minister may specify, such estimate as may be directed by the Minister of the incidence of dental caries in their functional area or in a specified part of their functional area, either with respect to all persons therein or to a specified class of such persons, and to furnish to the Minister particulars of such estimate as soon as may be after it is made.

(2) Nothing in this section shall be construed as imposing an obligation on any person to submit himself or any person for whom he is responsible to examination.

Construction of Health Services (Financial Provisions) Act, 1947

8. In its application to a service under this Act, subsection (2) of section 2 of the Health Services (Financial Provisions) Act, 1947, shall be construed as if "the date of the declaration," were substituted for "the 1st day of April next after the making of the declaration,"

Laying of regulations before Houses of the Oireachtas

9. Every regulation made by the Minister under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the regulation is passed by either such House within the next subsequent twenty one days on which that House has sat after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done thereunder.

Short title and collective citation

10. (1) This Act may be cited as the Health (Fluoridation of Water Supplies) Act, 1960.

(2) The Health Acts, 1947 to 1958, and this Act may be cited together as the Health Acts, 1947 to 1960.

Fluoridation Regulations, 1965

The provisions of the 1960 Act, following the conclusion of the legal proceedings in respect of the legislation, were brought into force in 1965 by a series of Statutory Instruments containing Ministerial Regulations. The following is an extract from one such instrument which has been edited in order to reduce repetitive matter.

S.I. No. 130 of 1965

FLUORIDATION OF WATER SUPPLIES (CORK) REGULATIONS, 1965.

The Minister for Health, having complied with subsection (4) of Section 2 of the Health (Fluoridation of Water Supplies) Act, 1960 (No. 46 of 1960) and having consulted with the Minister for Local Government, hereby makes the following Regulations :-

1. These Regulations may be cited, as the Fluoridation of Water Supplies (Cork) Regulations, 1965.
2. In these Regulations:
"the Minister" means the Minister for Health
"the Authority" means the Cork Health Authority.
3. The Authority shall arrange, in accordance with these Regulations, for the fluoridation of the public water supplies specified in the First Schedule to these Regulations.
4. (1) The Council of The County of Cork shall, as agent for the Authority, perform the following acts in relation to the fluoridation of water in the public water supplies referred to in paragraphs 8 to 23 of the First Schedule to these Regulations :-
 - (a) the provision, installation and maintenance of equipment for fluoridation,
 - (b) the making of arrangements for the addition of fluorine to the water, and
 - (c) the testing of the fluorine content of the water to which fluorine has been added.

Separate identical provisions in regard to each of the other individual sanitary authorities in County Cork are then made in Sections 4(2) to 4(8) inclusive.

5. The amount of fluorine which may be added to a water supply in accordance with these Regulations shall be such that the water, after the addition of the fluorine, shall contain not more than one part of fluorine per million parts of water and not less than eight-tenths of a part of fluorine per million parts of water.

6. Fluorine may be added to a public water supply in accordance with these Regulations either in the form of sodium fluoride complying with the specification for that substance in

the Second Schedule to these Regulations or in the form of sodium silicofluoride complying with the specification for that substance in the said Schedule or in the form of hydrofluosilicic acid complying with the specification for that substance in the said Schedule, or in such other form as may be approved by the Minister.

7. Equipment used for the fluoridation of the public water supplies specified in the First Schedule to these Regulations shall be such as may be specified or approved by the Minister for Local Government.

8. The fluorine content of each of the public water supplies specified in the First Schedule to these Regulations to which fluorine has been added shall be determined daily by a colorimetric method and in addition shall be determined by a distillation method at intervals not exceeding two weeks during the period of six months after the date on which fluorine shall have been first so added and thereafter at intervals not exceeding four weeks.

First Schedule

This lists the individual supplies for which the respective authorities are responsible.

Second Schedule

(1) Specification for Sodium Fluoride

The substance shall contain a minimum of 98 per cent. Sodium fluoride (NaF) by weight, providing 44.3 per cent available fluorine

The substance shall not contain any toxic or harmful impurities when dissolved, in water.

The content of insoluble material shall not exceed 0.5 per cent.

The moisture content shall not exceed 0.5 per cent.

The substance shall have a crystalline form (20-40 mesh particle size) and shall be free from dust.

(2) Specification for Sodium Silicofluoride

The substance shall contain a minimum of 98 per cent. Sodium silicofluoride (Na_2SiF_6) by weight, providing 59 per cent. available fluorine.

The substance shall not contain any toxic or harmful impurities when dissolved, in water.

The content of insoluble material shall not exceed. 0.5 per cent.

The moisture content shall not exceed 0.5 per cent.

The substance shall be in the form of a powder and shall conform to the following sieve tests:

- (a) 100 per cent to pass through a 40 mesh sieve;
- (b) 95 per cent to pass through a 100 mesh sieve; and
- (c) not less than 5 per cent nor more than 35 per cent to pass through a 325 mesh sieve.

(3) Specification for Hydrofluosilicic acid of 14 per cent strength

The acid as supplied shall contain 14 per cent by weight of fluosilicic acid (H_2SiF_6), subject to a tolerance of 0.5 per cent. Above or below that strength, and shall contain not more than 0.012 per cent, by weight "heavy metals" expressed as lead (Pb) and no other soluble mineral or organic substance in quantities capable of a deleterious or injurious effect upon health.

GIVEN under the Official Seal of
the Minister for Health this 16th
day of June One Thousand
Nine Hundred and Sixty-five.

L.S.

DONOGH O'MALLEY

MINISTER FOR HEALTH

Principal Fluoridated Water Supplies

Introduction

The following is a listing, in alphabetical order of sanitary authorities, of the principal public water supplies, which are fluoridated prior to distribution to consumers. The list has been prepared from the latest available data, and is comprehensive in its coverage. However, the reader should note, firstly, that some very small supplies may not have been included (for lack of confirmatory information) and secondly, that as a consequence of the ongoing improvement of national drinking water services, some 'free-standing' fluoridated supplies will have been incorporated into a larger regional water supply and as a consequence may not all be listed. Entries under the heading 'Principal Place(s) Served' have been made by the Forum and not by the Environmental Protection Agency and refer to water supplies which provide water to adjacent towns or townlands.

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Bray Urban Dist Council	Bray Town Supply (Vartry)	Bray
Carlow County Council	Bagenalstown	Bagenalstown
Carlow County Council	Borris	Borris
Carlow County Council	Carlow Central Regional	Ballon/Carlow/Myshall &c
Carlow County Council	Carlow North-West/Sion X	Carlow/Rathvilly &c
Carlow County Council	Hacketstown	Hacketstown
Carlow County Council	Tinnahinch	Tinnahinch
Carlow County Council	Tullow	Tullow
Cavan County Council	Bailieborough	Bailieborough
Cavan County Council	Ballyjamesduff Regional	Ballyjamesduff/Kilnaleck
Cavan County Council	Belturbet	Belturbet
Cavan County Council	Cavan Regional	Butlersbridge/Cavan &c
Cavan County Council	Cootehill	Cootehill
Cavan County Council	Kingscourt	Kingscourt
Clare County Council	Clarecastle	Clarecastle
Clare County Council	Clonlara/Parteen	Clonlara/Parteen
Clare County Council	Crusheen	Crusheen
Clare County Council	Ennistymon	Ennistymon
Clare County Council	Kildysart	Kildysart
Clare County Council	Kilkee	Kilkee
Clare County Council	Knockalisheen	Knockalisheen
Clare County Council	Lisdoonvarna	Lisdoonvarna
Clare County Council	Miltown Malbay	Miltown Malbay

Appendix 8 Principal Fluoridated Water Supplies

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Clare County Council	Scarriff	Scarriff
Clare County Council	Shannon/Sixmilebridge Reg	Shannon/Sixmilebridge
Clare County Council	West Clare Reg/Kilrush (New)	Kilrush &c
Clare County Council	West Clare Reg/Kilrush (Old)	Kilrush &c
Clonmel Corporation	Glenary	Clonmel
Clonmel Corporation	Poulavanogue	Clonmel
Cork Corporation	Cork City Supply	Cork
Cork Co Council (North)	Allow Regional	Freemount/Liscarroll &c
Cork Co Council (North)	Buttevant	Buttevant/Doneraile &c
Cork Co Council (North)	Castletownroche No 1	Castletownroche
Cork Co Council (North)	Charleville	Charleville
Cork Co Council (North)	Conna Regional	Conna area
Cork Co Council (North)	Fermoy	Fermoy
Cork Co Council (North)	Glanworth	Glanworth/Marshalstown
Cork Co Council (North)	Heatherside	Heatherside
Cork Co Council (North)	Mallow	Mallow
Cork Co Council (North)	Millstreet	Millstreet
Cork Co Council (North)	Mitchelstown (New)	Mitchelstown area
Cork Co Council (North)	Mitchelstown/Galtee	Mitchelstown area
Cork Co Council (North)	Mount North	Mount North
Cork Co Council (North)	Newmarket/Kanturk	Kanturk/Laharn/N'market &c
Cork Co Council (South)	Bandon Regional	Bandon
Cork Co Council (South)	Carrigaline	Carrigaline
Cork Co Council (South)	Cloyne/Aghada	Aghada/Cloyne &c
Cork Co Council (South)	Cobh Regional	Carrigtwohill/Cobh &c
Cork Co Council (South)	Cobh Urban	Cobh
Cork Co Council (South)	Donoughmore	Donoughmore
Cork Co Council (South)	Glanmire Regional	Glanmire &c
Cork Co Council (South)	Glashaboy/Little Island	Glashaboy/Little Island
Cork Co Council (South)	Inniscarra Regional	Ballincollig/Blarney/Curra- leigh/Dripsey/Inniscarra/ Ringaskiddy/ Waterfall &c
Cork Co Council (South)	Innishannon	Innishannon
Cork Co Council (South)	Kinsale	Kinsale
Cork Co Council (South)	Macroom Urban	Macroom
Cork Co Council (South)	Midleton Urban	Midleton
Cork Co Council (South)	Whitegate Regional	Whitegate
Cork Co Council (South)	Youghal Regional	Youghal

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Cork Co Council (West)	Baltimore	Baltimore/Castletownshend/ Tragumna &c
Cork Co Council (West)	Bantry	Bantry
Cork Co Council (West)	Castletownbere	Castletownbere/Eyeries &c
Cork Co Council (West)	Clonakilty	Clonakilty/Owenahincha &c
Cork Co Council (West)	Dunmanway	Dunmanway
Cork Co Council (West)	Skibbereen	Skibbereen
Donegal County Council	Buncrana	Buncrana
Donegal County Council	Bundoran	Bundoran
Donegal County Council	Cranford/Carrigart	Cranford/Carrigart
Donegal County Council	Creel/Creelbeg/Dunfanaghy	Creel/Creelbeg/Dunfanaghy
Donegal County Council	Donegal (River Eske)	Donegal Town
Donegal County Council	Frosses/Inver	Frosses/Inver
Donegal County Council	Glenties/Ardara	Glenties/Ardara
Donegal County Council	Gortahork/Falcarragh	Gortahork/Falcarragh
Donegal County Council	Inishowen East	Inishowen
Donegal County Council	Letterkenny	Letterkenny
Donegal County Council	Lettermacaward	Lettermacaward
Donegal County Council	Lough Mourne Regional	Lough Mourne area
Donegal County Council	Rosses Regional	Rosses
Drogheda Corporation	Rosehall	Drogheda
Drogheda Corporation	Staleen	Drogheda
Dublin Corporation	Ballyboden	Dublin City
Dublin Corporation	Ballymore Eustace	Dublin City
Dublin Corporation	Leixlip	Dublin City
Dublin Corporation	Roundwood	Dublin City
Dundalk Urb Dist Council	Cavan Hill/Castletown Mount	Dundalk
Dunlaoghaire/Rathdown CC	Ballyboden	Dunlaoghaire-Rathdown Co
Dunlaoghaire/Rathdown CC	Ballyedmonduff	Ballyedmonduff
Dunlaoghaire/Rathdown CC	Glencullen	Glencullen
Dunlaoghaire/Rathdown CC	Kiltiernan	Kiltiernan
Dunlaoghaire/Rathdown CC	Roundwood	Dunlaoghaire-Rathdown Co
Ennis Urban Dist Council	Ennis	Ennis
Fingal County Council	Leixlip	Fingal Co
Fingal County Council	Ballymore Eustace/Leixlip/ Roundwood	Fingal Co

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Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Galway Corporation	Galway (New Waterworks)	Galway City
Galway Corporation	Galway (Old Waterworks)	Galway City
Galway County Council	Athenry	Athenry
Galway County Council	Ballinasloe Regional	Ballinasloe
Galway County Council	Clarinbridge/Kilcolgan	Clarinbridge/Kilcolgan
Galway County Council	Clifden	Clifden
Galway County Council	Dunmore/Glenamaddy	Dunmore/Glenamaddy
Galway County Council	Galway City Regional	Galway City environs
Galway County Council	Killimor	Killimor
Galway County Council	Kinvara	Kinvara
Galway County Council	Loughrea Regional	Loughrea
Galway County Council	Mountbellew Regional	Mountbellew
Galway County Council	Oughterard Regional	Oughterard
Galway County Council	Portumna	Portumna
Galway County Council	Spiddal Regional	Spiddal
Galway County Council	Tuam	Tuam
Kerry County Council	Ardfert North/Ballyheigue	Ardfert North/Ballyheigue
Kerry County Council	Ardfert South/Fenit	Ardfert South/Fenit
Kerry County Council	Central Regional	Tralee/Central Kerry
Kerry County Council	Dingle	Dingle
Kerry County Council	Dromin Regional	Dromin
Kerry County Council	Inch Regional	Inch
Kerry County Council	Lyreacrompane/NE Kerry Reg	Lyreacrompane/NE Kerry
Kerry County Council	Mid-Kerry Regional	Mid County Kerry
Kildare County Council	Athy Urban	Athy
Kildare County Council	Ballytore/Moone/Timolin	Ballytore/Moone/Timolin
Kildare County Council	Leixlip Regional	Ardclough/Celbridge/ Kilcock/Leixlip/Maynooth/ Straffan
Kildare County Council	Monasterevan	Monasterevan
Kildare County Council	Poulaphouca Regional	Carbury/Clane/Derrinturn/ Johnstown/Kilcullen/Kildare/ Kill/Kilmeague/Naas/New- Bridge/Prosperous/ Rathangan/Robertstown &c
Kilkenny County Council	Ballyragget	Ballyragget
Kilkenny County Council	Bennettsbridge Regional	Bennettsbridge Regional
Kilkenny County Council	Callan	Callan

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Kilkenny County Council	Clogh/Castlecomer	Clogh/Castlecomer
Kilkenny County Council	Gowran/Goresbdge/Paulstown	Gowran/Goresbridge/Paulstown
Kilkenny County Council	Graiguenamanagh	Graiguenamanagh
Kilkenny County Council	Inistioge	Inistioge
Kilkenny County Council	Kilkenny (Radestown)	Kilkenny
Kilkenny County Council	Kilkenny (Troyswood)	Kilkenny
Kilkenny County Council	Mooncoin Regional	Mooncoin area
Kilkenny County Council	Piltown/Fiddown	Piltown/Fiddown
Kilkenny County Council	Thomastown	Thomastown
Kilkenny County Council	Urlingford/Johnstown	Urlingford/Johnstown
Laois County Council	Abbeyleix	Abbeyleix
Laois County Council	Clonaslee	Clonaslee
Laois County Council	Graigucullen	Graigucullen
Laois County Council	Mountmellick	Mountmellick
Laois County Council	Mountmellick	Mountmellick
Laois County Council	Portarlinton	Portarlinton
Laois County Council	Portlaoise	Portlaoise
Laois County Council	Rathdowney	Rathdowney
Leitrim County Council	Dromahaire	Dromahaire
Leitrim County Council	Drumkeerin	Drumkeerin
Leitrim County Council	Leitrim Village	Leitrim Village
Leitrim County Council	Manorhamilton	Manorhamilton
Leitrim County Council	South Leitrim Regional	Ballinamore/Carrick-on-Shannon/Dromod/Drumshanbo/Drumsna/Keshcarrigan/Mohill/Roskey &c
Limerick Corporation	Limerick City	Limerick City
Limerick County Council	Abbeyfeale Regional	Abbeyfeale Regional
Limerick County Council	Adare	Adare
Limerick County Council	Castletown/Ballyagran	Castletown/Ballyagran
Limerick County Council	Drumcollogher/SW Reg	Drumcollogher area
Limerick County Council	Foynes/Shannon Estuary Reg	Foynes area
Limerick County Council	Kilmallock	Kilmallock
Limerick County Council	Limerick City Environs	Limerick City Environs
Limerick County Council	Murroe/Barrington's Bridge	Murroe/Barrington's Bridge
Limerick County Council	Newcastlewest/Castlemahon	Newcastlewest/Castlemahon
Limerick County Council	Pallaskenry/Kildimo	Pallaskenry/Kildimo
Limerick County Council	Rathkeale	Rathkeale

Appendix 8 Principal Fluoridated Water Supplies

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Longford County Council	Ballinalee/Edgeworthstown	Ballinalee/Edgeworthstown
Longford County Council	Ballymahon Regional	Ballymahon area
Longford County Council	Granard Regional	Granard area
Longford County Council	Lanesboro Regional	Lanesboro area
Longford County Council	Longford Central Regional	Longford
Longford County Council	Lough Gowna Regional	West Longford
Louth County Council	Ardee	Ardee
Louth County Council	Greenmount	Greenmount
Mayo County Council	Ballina Regional	Ballina and environs
Mayo County Council	Ballyhaunis	Ballyhaunis
Mayo County Council	Belmullet Regional	Belmullet/Bangor Erris &c
Mayo County Council	Kiltimagh	Kiltimagh
Mayo County Council	Lough Mask Regional	Castlebar &c
Mayo County Council	Swinford	Swinford
Mayo County Council	Westport	Westport
Meath County Council	Ballivor	Ballivor
Meath County Council	Drumconrath	Drumconrath
Meath County Council	Dunboyne/Clonee	Dunboyne/Clonee
Meath County Council	Dunshaughlin (New)	Dunshaughlin
Meath County Council	East Meath Regional	Bettystown/Duleek/Dunshaughlin/ Ratoath/Stamullen &c
Meath County Council	Navan/Mid-Meath Regional	Navan & environs
Meath County Council	Trim	Trim
Monaghan County Council	Carrickmacross	Carrickmacross
Monaghan County Council	Castleblayney	Castleblayney
Monaghan County Council	Clones	Clones
Monaghan County Council	Lough Egish Regional	Lough Egish area
Monaghan County Council	Monaghan Town	Monaghan Town
Offaly County Council	Banagher	Banagher
Offaly County Council	Birr	Birr
Offaly County Council	Clara	Clara
Offaly County Council	Daingean	Daingean
Offaly County Council	Ferbane	Ferbane
Offaly County Council	Rahan (Hollimshill)	Rahan
Offaly County Council	Rhode	Rhode
Offaly County Council	Shannonbridge	Shannonbridge
Offaly County Council	Tullamore	Tullamore

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Roscommon Co Council	Ballinlough/Loughglynn Reg	Ballinlough/Loughglynn
Roscommon Co Council	Ballyleague Regional	Ballyleague
Roscommon Co Council	Boyle/Ardcarne Regional	Boyle/Ardcarne
Roscommon Co Council	Castlerea Regional	Castlerea area
Roscommon Co Council	Castlerea Urban	Castlerea Town
Roscommon Co Council	Cortober Regional	Cortober &c
Roscommon Co Council	Mount Talbot/Four Roads Reg	Mount Talbot/Four Roads
Roscommon Co Council	North-East Roscommon Reg	North-East Roscommon
Roscommon Co Council	North Roscommon Regional	North Roscommon
Roscommon Co Council	Roscommon Central Regional	Central Roscommon
Roscommon Co Council	South Roscommon Regional	South Roscommon
Sligo Corporation	Sligo Town	Sligo Town
Sligo County Council	Ballymote Regional	Ballymote & environs
Sligo County Council	Kilsellagh	Ballinode/Rosses Point &c
Sligo County Council	Lough Easkey Regional	Easkey/Enniscrone/Templeboy
Sligo County Council	Lough Gill Regional	Ballysodare/Collooney/Sligo/ Strandhill &c
Sligo County Council	Lough Talt Regional	Aclare/Ballinacarrow/ Bunninadden/Coolaney &c
Sligo County Council	North Sligo Regional	Cliffoney/Grange/Mullaghmore
Sligo County Council	South Sligo Regional	Gurteen/Tubbercurry &c
South Dublin Co Council	Ballyboden	South Dublin Co
South Dublin Co Council	Ballymore Eustace	South Dublin Co
South Dublin Co Council	Brittas	South Dublin Co
Tipperary (NR) Co Council	Borrisokane Regional	Borrisokane
Tipperary (NR) Co Council	Borrisoleigh/Drom	Borrisoleigh/Drom
Tipperary (NR) Co Council	Cloughjordan	Cloughjordan
Tipperary (NR) Co Council	Nenagh	Nenagh
Tipperary (NR) Co Council	Newport Regional	Newport
Tipperary (NR) Co Council	Roscrea Regional	Roscrea
Tipperary (NR) Co Council	Templemore	Templemore
Tipperary (NR) Co Council	Thurles	Thurles
Tipperary (SR) Co Council	Ardfinnan Regional	Ardfinnan
Tipperary (SR) Co Council	Cahir (Reservoir)	Cahir
Tipperary (SR) Co Council	Carrick-on-Suir (Crotty's L)	Carrick-on-Suir
Tipperary (SR) Co Council	Carrick-on-Suir (R Lingaun)	Carrick-on-Suir
Tipperary (SR) Co Council	Cloran Regional	Cloran area

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Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Tipperary (SR) Co Council	Dundrum Regional	Dundrum
Tipperary (SR) Co Council	Galtee Regional	South Tipperary
Tipperary (SR) Co Council	Gortnapisha Regional	Gortnapisha area
Tipperary (SR) Co Council	Ironmills/Cappawhite	Ironmills/Cappawhite
Tipperary (SR) Co Council	Killurney	Killurney
Tipperary (SR) Co Council	Mullenbaun	Mullenbaun
Tipperary (SR) Co Council	Tipperary Urban	Tipperary Town
Waterford Corporation	East Waterford Regional	Waterford City
Waterford County Council	Dungarvan Urban	Dungarvan
Waterford County Council	East Waterford Regional	East Waterford
Waterford County Council	Helvick/Ring/Seaview	Helvick/Ring/Seaview
Waterford County Council	Lismore/Cappoquin/Ballyduff	Lismore/Cappoquin/Ballyduff
Waterford County Council	Tramore/Dunmore East	Tramore/Dunmore East
Westmeath County Council	Athlone Urban	Athlone
Westmeath County Council	Castlepollard	Castlepollard
Westmeath County Council	Moate	Moate
Westmeath County Council	Mullingar Regional (Hi Level)	Dysart/Horseleap/Kilbeggan/ Rochfortbridge &c
Westmeath County Council	Mullingar Regional (Lo Level)	Bunbrusna/Kinnegad/Rathowen
Westmeath County Council	Mullingar Town (Indep Supp)	Mullingar
Wexford County Council	Bunclody	Bunclody
Wexford County Council	Fardystown Regional	Drinagh/Killinick/Kilrane/ Murrintown/Rosslare/Tagoat &c
Wexford County Council	Ferns Regional	Ferns area
Wexford County Council	Gorey Regional	Ballycanew/Ballygarrett/Cahore/ Clogh/Courtown/Gorey &c
Wexford County Council	Kilmuckridge Regional	Ballygarron/Kilmuckridge/ Morriscastle &c
Wexford County Council	New Ross	New Ross
Wexford County Council	South Wexford Regional	Ballycullane/Ballyhack/ Bridgetown/Campile/ Duncannon/Duncormick/ Fethard/KilmoreQuay/ Ramsgrange/Wellingtonbridge
Wexford County Council	Sow Regional	Blackwater/Castlebridge/ Crossabeg/Curraclloe/ Ferrybank/Oylegate &c
Wexford County Council	Wexford Town	Wexford

Sanitary Authority	Fluoridated Supply	Principal Place(s) Served
Wicklow County Council	Arklow	Arklow
Wicklow County Council	Blessington	Blessington
Wicklow County Council	Enniskerry/Millfield/Kilgarron	Enniskerry area
Wicklow County Council	Glenealy	Glenealy
Wicklow County Council	Greystones/Delgany/K'incarrig	Greystones area
Wicklow County Council	Kilmacanogue/Kilcoole	Kilmacanogue/Kilcoole
Wicklow County Council	Laragh/Annamoe	Laragh/Annamoe
Wicklow County Council	Newcastle/Newtnmtkennedy	Newcastle/ Newtownmountkennedy
Wicklow County Council	Tinahely Regional	Tinahely/Carnew &c
Wicklow County Council	Wicklow	Wicklow
Wicklow County Council	Windgates/Tempolecarrig	Windgates/Tempolecarrig

General Legislation Concerning Fluoride

Although there are references to legislative enactments concerning fluoride throughout this Report the details have been collated in the following table, for the convenience of the reader:

Title of Enactment	Date	Official Reference	Remarks
Health (Fluoridation of Water Supplies) Act, 1960	28.12.1960	Number 46 of 1960	Note 1
Council Directive of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States	16.06.1975	75/440/EEC	Note 2
Council Directive of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	04.05.1976	76/464/EEC	Note 3
Council Directive of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances	17.12.1979	80/68/EEC	Note 4
Council Directive of 15 July 1980 relating to the quality of water intended for human consumption	15.07.1980	80/778/EEC	Note 5
European Communities (Quality of Water Intended for Human Consumption) Regulations, 1988	29.04.1988	SI No 81 of 1988	Note 6
European Communities (Quality of Surface Water Intended for the Abstraction of Drinking Water) Regulations, 1989	10.11.1989	SI No 294 of 1989	Note 7

Council Directive of 3 November 1998 relating to the quality of water intended for human consumption	03.11.1998	98/83/EC	Note 8
European Communities (Drinking Water) Regulations, 2000	18.12.2000	SI No 439 of 2000	Note 9
Water Quality (Dangerous Substances) Regulations, 2001	30.01.2001	SI No 12 of 2001	Note 10

Notes

- 1 This 1960 Act is the primary legislation governing the fluoridation of public drinking water supplies in Ireland. While it prescribes the concentration range for fluoride in fluoridated drinking water, it specifies administrative and technical procedures in connection with fluoridation. Its provisions are still in force. In contrast to this Act, all the other legislative provisions listed are almost exclusively concerned with permissible concentrations in the aquatic environment.
- 2 Referred to colloquially as the 'Surface Water Directive', this enactment limits the amount of fluoride which may be present in surface waters which serve as 'raw water' sources for drinking water. This is because most conventional treatment processes will not reduce raw water fluoride levels.
- 3 Known as the 'Dangerous Substances Directive', this is discussed briefly in Appendix 10, 'Fluoride and the Aquatic Environment'. It is a so-called 'framework' Directive in that it forms the basis for a series of other Directives and pollution control measures.
- 4 Also discussed in Appendix 10, the 'Ground Water Directive' has many affinities with the Dangerous Substances Directive.
- 5 This is the first 'Drinking Water Directive'. Its provisions are still in force and are being implemented, but they will become ineffective as from 1 January 2004 when a new Directive comes into operation (see below).
- 6 These Regulations transposed the provisions of the 1980 Drinking Water Directive into Irish Law. It should be noted in the interval between the adoption of the Directive and the making of the national Regulations, a regulatory procedure was in force but the formal making of Regulations was subsequently considered necessary.
- 7 These Regulations transposed the provisions of the 1975 Surface Water Directive into Irish Law. It should be noted in the interval between the adoption of the Directive and the making of the national Regulations, a regulatory procedure was in force but the formal making of Regulations was subsequently considered necessary.

- 8 The provisions of the 1998 Directive – as transposed by the 2000 Regulations – will (by 1 January 2004) supplant those of the 1980 Directive, as transposed by the 1988 Regulations. The former differs greatly from the latter in its structure and content and reflects a thorough reappraisal and revision of the steps necessary to protect the health of the drinking water consumer.
- 9 As did the 1988 Regulations, those adopted in 2000 transpose the detailed provisions of the new Drinking Water Directive into Irish law. In practical terms, the national Regulations – which cannot be in any way less stringent than the Directive – replace the Directive and become the primary legislation which must be followed.
- 10 These Regulations are discussed in Appendix 10 (q.v.).

Fluoride and the Aquatic Environment

Introduction

When the question of fluoride is raised in connection with water, it is almost always in the context of its presence in drinking water, whether naturally or as a consequence of its addition in the final stage of the raw water treatment process. Very rarely is the environmental or sanitary engineer or scientist faced with the implications of fluoride presence in the water environment as a whole, and of its possible effects on aquatic flora and fauna. Nonetheless, there are legislative provisions limiting the presence of fluoride in the aquatic environment and the Forum would be remiss not to include a summary of the position. This view is supported by the opinions of several respondents to the public consultation undertaken by the Forum. There is also considerable research activity in this field worldwide.

It should be stated at the outset that in Ireland the effects of fluoride on the general environment and on the aquatic environment in particular are imperceptible. The main channel of access for fluoride to the environment in this country is via wastewater, primarily domestic sewage. Unlike some European countries where population distribution and urban economics permit the provision to domestic premises (which, to a great degree, consist of apartment blocks rather than dispersed houses) of parallel potable (drinkable) and non-potable water supplies, the position in Ireland and Britain is that the consumer receives a single supply of water which has been treated to make it suitable for drinking, cooking and other person-related uses. This single supply is used for all purposes, including the many uses which do not require potable quality.

A consequence of this is that virtually all the fluoride reaching a consumer's premises in the public water supply will ultimately be discharged in the domestic wastewater. In time, following the treatment processes applied to the waste (which, it should be noted, will not materially reduce the levels of fluoride present), the fluoride will be discharged to a 'receiving water' such as a lake, river or stream. There, the waste will be diluted – normally hundreds of times at least – and the fluoride levels will be reduced far below the threshold levels for the various compartments of the aquatic environment.

While this Report cannot address the complex matters of wastewater treatment and the at times very apparent deleterious effects of untreated or incompletely treated wastes on receiving waters, especially in times of low flow, it should be stated that the absolute minimum acceptable dilution factor for a waste discharged to water is eight, i.e. the waste, when treated at normal level, must receive an eight-fold dilution. Clearly, if the waste has received a lesser degree of treatment the requisite degree of dilution must be far greater.

However, in the case of fluoride which will 'survive' the treatment processes, the eight-times dilution is the lowest 'worst case' dilution permissible. Such a minimum dilution will ensure that fluoride levels will fall below the limits prescribed for the aquatic environment. It may

be added that normal dilution factors for waste discharges to receiving waters are vastly greater than eight.

Environmental Standards for Fluoride

Until very recently there were no express standards for fluoride in environmental waters in Ireland. The long-standing limits in the National Regulations made by the Minister for the Environment for the transposition of the Surface Water Directive (75/440/EEC) and the Drinking Water Directive (80/778/EEC) into Irish law are both applicable to drinking water, raw in one case and treated in the second.

However, the relevance of fluoride presence in the broader aquatic environment was not overlooked in European Community legislation, and fluoride is listed as an undesirable substance in the important Dangerous Substances Directive (76/464/EEC) and the closely related Ground Water Directive (80/68/EEC). While the present context is inappropriate to a discussion of what is a very complex aspect of environmental protection, it must be pointed out that, in contrast to the initial series of 'water directives' which set specific limits for various ranges of chemical and other parameters in water, the two Directives just cited differ greatly in their approach.

Briefly, instead of laying down maximum concentrations for dangerous substances in environmental waters, these Directives listed such substances in one of two categories, in an annex to the Directive itself. The first category – designated as 'List I' but widely referred to as the 'Black List' – comprises substances the discharges of which must be authorised and rigorously controlled as to eliminate any pollution caused by them. List I contains such materials as organotin compounds, mercury and cadmium, for example. These are highly toxic, noxious materials the presence of which in the environment is clearly wholly unacceptable.

The second category – 'List II' (the 'Grey List') – adopts a similar emission control approach and applies to substances pollution by which must be reduced. While constituting a lesser hazard than those in List I, List II materials are also highly undesirable and include a range of metals, ammonia and – relevant to the present discussion – fluoride. Both the Dangerous Substances and Ground Water Directives have List I/List II annexes and they are almost identical. Fluoride is specified as a List II material in either case.

The adoption of these Directives by the European Community was regarded as merely the first stage of an environmental control procedure which would in time lead to specific controls on the various listed materials. In the event, further developments turned out to be both complex and quite slow-moving, with initial attention being paid to the List I substances. Suffice it to say here that Irish Dangerous Substances Regulations were made early in 2001; they cover a total of fourteen substances including fluoride.¹⁴⁶

The function of setting environmental standards in Ireland is reserved to the Minister for the Environment and Local Government, whose Department will have exhaustively researched

the matter before recommending possible standards for adoption by the Minister. All such environmental questions are, of their nature, extremely complex and the apparent simplicity of a single limit belies the wide-ranging investigations which must be carried out in order to arrive at an acceptable limit value.

The following are the standards prescribed in the 2001 Regulations for fluoride and for some metals, which are discussed in the present Report in connection with fluoride.

Metals and Other Substances

Substance	Standard for Fresh Waters ($\mu\text{g}/\text{litre}$) Hardness of water ($\text{mg}/\text{litre CaCO}_3$)		Standard for Tidal Waters ($\mu\text{g}/\text{litre}$)
	≤ 100	>100	
Arsenic	25	25	20
Chromium	5	30	15
Fluoride	500	500	1500
Lead	5	10	5
Nickel	8	50	25

While the resolution of general environmental questions lies wholly outside the remit of the Forum on Fluoridation, the Forum is aware from the public consultation of interest in the possible effects of fluoridation on the aquatic environment. In the preparation of its Report the Forum has made extensive use of the scientific literature, on all aspects of its brief. A source in the environmental field which the Forum found useful and which it considers to be of likely value to interested members of the public is a publication – *Ambient Water Quality Criteria for Fluoride* – by the Ministry of Environment for the Province of British Columbia, Canada.¹⁴⁷

This deals in detail with all the key compartments of the aquatic environment and contains over 350 references from relevant world wide literature. The volume is commendable for its comprehensive content and the clarity of its presentation. However, the Forum must state that it cites this work as a potential aid to the public and that this does not constitute an endorsement of the publication or its contents. It may be of interest to quote from *Ambient Water Quality Criteria for Fluoride* the recommended fluoride criteria for a range of water uses.

Summary Table of Recommended Criteria for Fluoride
(All values as mg/litre F) (parts per million)

Water Use	Criteria
Raw Drinking Water	1.0 as a 30-day mean 1.5 as a maximum
Aquatic Life-Fresh*	0.2 as a maximum where the water hardness ≤50 mg/L
Aquatic Life-Marine	0.3 as a maximum where water hardness >50 mg/L 1.5 as a maximum
Wildlife	1.0 as a 30-day mean 1.5 as a maximum
Dairy cows, breeding stock and other long-lived animals	1.0 as a 30-day average 1.5 as a maximum
All other livestock on a normal diet	2.0 as a 30-day average 4.0 as a maximum
Livestock receiving high fluoride mineral or bone meal feed additives	1.0 as a 30-day average 2.0 as a maximum
Irrigation for all soils	1.0 as a 30-day average
Recreation	None set
Industrial uses such as beer, beverage and processed food manufacture and packaging	1.0 as a 30-day mean 1.5 as a maximum

* This is an interim criterion until carefully controlled experiments can determine the appropriate levels of fluoride under various combinations of water temperature and hardness, measured as calcium carbonate.

It will be noted that the table of criteria and its accompanying notes refer to both water temperature and hardness. This reflects the fact that in the case of some important contaminants of water – especially heavy metals – the toxic effects of such substances can vary greatly with hardness, in particular. Generally, the less hard a water is the greater the toxic effects of the given substances. In the case of fluoride, the ambient temperature of the water influences its effects. This is reflected in the 1980 Drinking Water Directive, for example, where differing fluoride/temperature figures are specified. In the Irish climate, where temperature variations are not extreme, it has been practicable to set a single fluoride level without a temperature qualification.

HFSA Manufacture - A Summary

Hydrofluorosilicic acid (H_2SiF_6) is obtained by the reaction between hydrofluoric acid and silica. Fluorspar rock is treated with sulphuric acid to produce hydrofluoric acid and calcium sulphate.



This reaction, which is endothermic (needing heat input), takes place in a rotary kiln, with indirect heating. The HF comes out of the kiln continuously as a gas, while the CaSO_4 comes out in solid form. The gas (HF) is washed and cooled in a packing tower; once purified, it passes to condensation by means of a battery of refrigerated condensers in series. Any uncondensed gases go through a triple purification system before their emission into the atmosphere free of HF.

The HF (liquid) is finally purified in a continuously operated rectifying column, and it is commercially known as 'anhydrous hydrofluoric' acid. (The hydrofluoric acid is also marketed commercially in different concentrations and qualities, such as HF 70/75 per cent, HF 60 per cent, HF 40 per cent, Analytical Grade etc.) The HF is then reacted with quartz (the silica source):



HFSA with a concentration of 37 to 42 per cent is produced. The chemical reaction takes place in a reactor lined with Teflon, preventing potential contamination with metallic parts of the equipment. This is essential as the H_2SiF_6 is registered in the Spanish Health Ministry as a food additive.

Product Data	Hydrofluorosilicic Acid	
Description	Aqueous solution of H_2SiF_6 , transparent to pale yellow in colour.	
Identification	EINECS No.: 241-034-8; UN No.:1778; CAS No.:16961-83-4	
Purity	37 to 42%	
Chemical analysis	H_2SiF_6	39% Typical value
	HF (Free)	2% max.
	SO_4	0.4% max.
	Heavy metals (expr as Pb)	0.02% max.
	As	0.0005% max.

Physical properties	Density (approx.)	1.34 to 1.40 Kg/L
	State	Liquid
	Odour	Pungent
	Boiling point	1120 C
	Solubility in water	Miscible

Risks	Classification for transport:
	TPC class 8.8.b
	ADR class 8.9.b
	TPF class 8.9.b
	RID class 8.9.b
IMCO class 8.	

The chemical constituents of Fluorspar rock are as follows:

Chemical characteristics of Fluorspar	
CaF ₂	97.0% min
SiO ₂	1.0% max
M. Organica	0.05% max
P ₂ O ₅	300 ppm max
H ₂ O	10% max.
CaCO ₃	1.0% max
Sulfuro	0.01% max
As	3 ppm max
P. Acetico	1.4% max
BaSO ₄	0.255 max
Oxidos Metalicos	0.5% max
Fe	700 ppm
Zn	100 ppm
Pb	100 ppm

The chemical constituents of Quartz are as follows:

Chemical characteristics of Quartz	
SiO ₂	98% max
Al ₂ O ₃	0.6% max
Hierro (expressed as Fe ₂ O ₃)	0.1% max
Calcium (expressed as CaO)	0.5% max
Magnesium expressed as MgO)	0.05% max
Sodium expressed as Na ₂ O	0.02% max
Potassium (expressed as K ₂ O)	0.2% max
Titanium (expressed as TiO ₂)	0.1% max
Pérdida por calcinación (loss by calcination)	0.5% max

Quality Control of HFSA

The analysis of hydrofluorosilicic acid at various concentrations is performed by Enterprise Ireland on behalf of the Eastern Regional Health Authority. The methods employed are as follows:

Approximate density - known volumes of the sample are weighed at room temperature and the approximate density is calculated.

Metals content - Lead, arsenic, chromium, cadmium, nickel, selenium, mercury, antimony and phosphorus: portions of the sample are acidified and elements specified determined by Inductively Coupled Plasma (ICP) Spectrometry.

Silicon content - portions of the samples are diluted and the silicon content determined by Inductively Coupled Plasma (ICP) Spectrometry.

Fluoride content - the fluoride content is determined by means of the ion specific electrode.

The following results were obtained from samples taken in February 2001.

Sample Identification	Storage Tanks in New Ross					Day Tank in water plant 14%
	40%	40%	40%	14%	14%	
Approx. density	1.412	1.407	1.410	1.118	1.118	1.135
% Fluoride	34.6	35.6	34.5	12.2	11.8	11.8
% H ₂ SiF ₆	43.7	45.0	43.6	15.4	14.9	14.9
% Silicon	8.8	8.7	8.7	3.05	2.98	2.84
Arsenic mg/kg	1.0	1.1	1.2	<1	<1(0.9)	<1
Mercury mg/kg	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Chromium mg/kg	0.14	0.09	0.15	4.1	5.8	0.15
Zinc mg/kg	0.05	0.04	0.08	0.07	0.07	0.08
Cadmium mg/kg	<0.5	<0.5	<0.5	<0.05	<0.05	<0.05
Lead mg/kg	5.7	6.1	5.4	2.4	2.5	3.0
Nickel mg/kg	0.11	0.08	0.11	1.9	4.0	0.11
Iron mg/kg	2.2	1.9	2.5	15	20	2.3
Selenium mg/kg	<1	<1	<1	<1	<1	<1
Antimony mg/kg	<1	<1	<1	<1	<1	<1
Phosphorus mg/kg	62	62	62	22	22	23
Phosphate as P ₂ O ₅ mg/kg (calculation)	280	280	280	100	100	105

Heavy Metals Concentrations in HFSA

There have been many expressions of public concern regarding the presence of heavy metals, notably arsenic and lead, in the hydrofluorosilicic acid (HFSA), which is used in Ireland to fluoridate drinking water. Some media reports have given members of the public the wholly erroneous impression that such noxious substances pose a hazard to the consumer of fluoridated drinking water, and this has been a matter of no little concern to the Forum. Accordingly, the Forum decided to investigate the metals content of a small number of samples of the raw fluoridation additive, HFSA. Three random samples of HFSA as used in Ireland were analysed for a range of eight heavy metals. On completion of the analyses a risk assessment was prepared. This is presented in the table below.

This assessment shows that, at the concentrations of the respective metals which would result in drinking water after the additive had been diluted to the upper limit of 1.0 parts per million fluoride, there would be no appreciable toxic effects. The residual metals concentrations would be a tiny fraction of the guideline values recommended by the World Health Organisation. (These WHO values are presented in the table mentioned.) It may be noted that the EU Drinking Water Directive (98/83/EC), adopted on 3 November 1998,¹ also prescribes so-called 'parametric values' or standards for heavy metals concentrations in drinking water. These will replace the current standards as from 01 January 2004.

EU DRINKING WATER DIRECTIVE : STANDARDS FOR HEAVY METALS

Heavy Metal	1980 Directive/ 1988 Regulations (a)	1998 Directive/ 2000 Regulations (b)
Arsenic	0.05 mg/litre (50 µg/litre) As	0.01 mg/litre (10 µg/litre) As
Mercury	0.001 mg/litre (1 µg/litre) Hg	0.001 mg/litre (1 µg/litre) Hg
Chromium	0.05 mg/litre (50 µg/litre) Cr	0.05 mg/litre (50 µg/litre) Cr
Cadmium	0.005 mg/litre (5 µg/litre) Cd	0.005 mg/litre (5 µg/litre) Cd
Lead	0.05 mg/litre (50 µg/litre) Pb	0.01 mg/litre (10 µg/litre) Pb*
Nickel	0.05 mg/litre (50 µg/litre) Ni	0.02 mg/litre (20 µg/litre) Ni
Selenium	0.01 mg/litre (10 µg/litre) Se	0.01 mg/litre (10 µg/litre) Se
Antimony	0.01 mg/litre (10 µg/litre) Sb	0.005 mg/litre (5 µg/litre) Sb

* The limit shown will apply in 2013. There is an interim limit of 0.025 mg/litre (25µg/litre)

(a) In effect to 31 December 2003.

(b) In effect from 01 January 2004.

It will be recalled that 1 mg/litre is equivalent to one part per million; 1 microgram/litre (µg/l) is one-thousandth of 1 part per million.

Risk Assessment of Heavy Metal in HFSA

Heavy Metal	Average Test Result in 3 Samples of HFSA from Spain *	Dilution factor used in ensuring 1 ppm F in water by volume	Metal concentration in water due to HFS acid after fluoridation	W.H.O. drinking water guideline for metal	Metal concentration as a % of W.H.O. guideline
	mg/kg	-	mg/l	mg/l	-
Arsenic	1.10	352,000	0.0000031	0.01	0.031%
Mercury (B)	0.50	352,000	0.0000014	0.001	0.142%
Chromium	0.13	352,000	0.0000004	0.05	0.001%
Cadmium (B)	0.05	352,000	0.0000001	0.003	0.005%
Lead	5.70	352,000	0.0000162	0.01	0.162%
Nickel	0.10	352,000	0.0000003	0.02	0.001%
Selenium (B)	1.00	352,000	0.0000028	0.01	0.028%
Antimony (B)	1.00	352,000	0.0000028	0.005	0.057%
Fluoride	352000.00	352,000	1.0000000	-	-

Heavy Metal	J.E.C.F.A. provisional tolerable weekly intake of metal per kilogram body weight	E.U. Scientific Committee for Food Adult weight parameter	J.E.C.F.A. provisional tolerable weekly intake of metal per adult	Volume of water an adult would need to consume in a week to exceed J.E.F.C.A. Safety Levels (PWT) (A)
	mg/kg	body weight kg	mg	Litres
Arsenic	0.015	60	0.9	288,000
Mercury (B)	0.005	60	0.3	211,200
Chromium	No value set	-	-	-
Cadmium (B)	0.007	60	0.42	2,956,800
Lead	0.025	60	1.5	92,632
Nickel	No value set	-	-	-
Selenium (B)	No value set	-	-	-
Antimony (B)	No value set	-	-	-
Fluoride	-	-	-	-

(A) Assuming that water is the sole source of exposure

(B) These values are below the limit of detection and are assigned a value at the limit of detection as a worst case scenario.

J.E.C.F.A. = FAO Joint Expert Committee on Food Additives W.H.O. = World Health Org.

The heavy metal analysis shows that the levels of heavy metal contaminants in hydrofluorosilicic acid are sufficiently low that there would be no appreciable toxic effects as a result of exposure to these contaminants via fluoridated water. All parameters are less than 0.5% of the WHO guidelines for tolerable heavy metal content of drinking water.

* Data from Dublin Region Public Analyst

The Treatment of Drinking Water

Drinking Water

Water is essential to sustain life, and a satisfactory supply must be made available to consumers. Every effort should be made to achieve a drinking water quality as high as practicable. Protection of water supplies from contamination is the first line of defence. Source protection is almost invariably the best method of ensuring safe drinking water and is to be preferred to treating a contaminated water supply to render it suitable for consumption. The protection of the source from pollution and the provision of adequate and properly operated treatment processes constitute the essential barriers to the transmission of disease on which the supply of wholesome water depends.⁸⁴ Raw water is rendered suitable for human consumption by a number of treatment processes.

Water Treatment Processes

As stated above, the fundamental purpose of water treatment is to protect the consumer from disease caused by pathogens (harmful micro-organisms) and from impurities in the water that may be either injurious to human health or offensive. These purposes are achieved by introducing successive barriers, such as coagulation, sedimentation and filtration to remove pathogens and impurities. The final barrier is disinfection. The function of the entire treatment process may be regarded as that of conditioning the water for effective and reliable disinfection. The various elements of treatment are explained briefly below.

Coagulation and flocculation

To remove particulate matter, a water treatment plant will generally include equipment for coagulation and flocculation, followed by sedimentation and filtration. Coagulation involves the addition of chemicals (e.g. aluminium sulphate, ferric sulphate) to neutralise the tiny electric charges on suspended particles and facilitate their agglomeration during the slow mixing provided in the flocculation step. Flocs thus formed co-precipitate, absorbing and entrapping natural colour and mineral particles, and can bring about major reductions in counts of protozoa, faecal bacteria, pathogens and viruses.

Coagulation and flocculation require a high level of operational skill. Chemical dosages and pH control must be correct, and the plant must be designed to ensure proper floc formation.

Sedimentation or flotation

The purpose of sedimentation is to permit settleable floc to be deposited and thus reduce the concentration of suspended solids that must be removed by filters. Flotation is an alternative, and may be used when the amount of floc is small.

Rapid sand filtration

Rapid sand filters consist of 0.4 to 1.2 metres of sand, usually of a size of 0.5 to 1.0 mm, supported by gravel and underdrains. During filtration, residual particles of the floc not removed by sedimentation are trapped in the interstices of the bed, and may induce further flocculation of particles. The filters are normally cleaned by reversal of the flow through the sand bed (backwashing). The backwash water is either discharged to the sewer or drying beds or recycled after removal of sludge.

Slow sand filtration

Typically, slow sand filters consist of 0.5 to 1.5 metres of silica with an effective size of 0.3 to 0.6 mm. Slow sand filtration is simpler to operate than rapid filtration, as frequent backwashing is not required. It is therefore particularly suitable for developing countries and small rural schemes. The filters, however, are readily clogged by algal blooms and they do not remove metals and many micropollutants efficiently. They effectively remove biodegradable organic carbon and they oxidise ammonia.

When the filter is first brought into use, a microbial slime community (*schmutzdecke*) develops at the surface of the bed. This consists of bacteria, free-living ciliated protozoa and amoeba, crustacea, and invertebrate larvae acting in food chains, resulting in the oxidation of organic substances in the water and of ammoniacal nitrogen to nitrate. Pathogenic bacteria, viruses and resting stages of parasites are removed, principally by absorption on to the *schmutzdecke* and by subsequent predation.

Disinfection

The overall objective of disinfection is to ensure that the quality criteria contained in drinking water regulations are always met. Terminal disinfection of piped drinking water supplies is of paramount importance, since it is the final barrier to the transmission of waterborne bacterial and viral diseases. Chlorine and hypochlorite are the most frequently used agents; however, water may also be disinfected with chloramines, chlorine dioxide, ozone and ultraviolet irradiation. The efficiency of any disinfection process will depend on the degree of purity achieved by prior treatment, as disinfectants are highly active and will be neutralised to a greater or lesser extent by organic matter and readily oxidisable compounds in water.

Technical Guidelines

The Forum made recommendations on the need for guidelines/codes of practice for all involved in the water fluoridation process. The technical content of these has been suggested by the DoELG and deals with the following:

- Security of installation
- Delivery and storage facilities including level indication and fill systems
- Bunding and secondary containment of bulk and day tank storage
- Materials suitable for contact with 14 per cent hydrofluorosilicic acid, or other strengths as appropriate
- Personal protection equipment
- Ventilation
- Safety issues including emergency wash and eye rinse facilities
- Valving arrangements (failsafe)
- Dosing pump arrangement (duty/stand-by, suction lift and anti-siphonage arrangements, pump selection and operating points)
- Dosing arrangements (flow proportional or volume over time) and interlocks with other pumping plant
- Calibration of dosing pumps, meters and weighing scales
- Plant maintenance guidelines and maintenance contracts (yearly inspection and service by specialist contractor).

Presentations by Professor William Binchy

Fluoridation: The Legal Dimension

When examining the legal dimensions of the provision of fluoridation through the water supply, one encounters a fascinating complexity of important issues regarding the relationship between the State and the citizen and the reconciliation of the norms of welfare and paternalism with those of autonomy, privacy, bodily integrity and human dignity. Encapsulated in this narrow aspect of health policy are some of the crucial questions of how democratic society is to accommodate differing perceptions of what is good for citizens, who should decide what is good and ultimately whose views should prevail.

The legal answers to these questions are largely framed in terms of an analysis of the Irish Constitution. On first consideration, the answers are clear. There is judicial authority in respect of the Constitution which seems to put the matter beyond debate. In *Ryan v Attorney General*¹, the Supreme Court, affirming Kenny J's judgment in the High Court, upheld the validity of legislation providing for the fluoridation of water supplied to the public. It is also worth noting that, in *Association X v United Kingdom*², the European Commission of Human Rights upheld a nationwide programme of vaccination of children on the basis that the adverse reactions were miniscule compared with the millions of vaccinations given each year and that the state in question had established a system of control and supervision of the programme which was consistent with the requirements of Article 2 of the European Convention on Human Rights.

It would be mistaken, however, to assume that further legal analysis of the issue is foreclosed. This is for two reasons, one empirical, the other normative.

So far as the empirical dimension is concerned, the issues surrounding the safety and health implications of providing fluoridation in the public water supplies are always subject to being revisited by the judiciary. In *Ryan*³, Ó Dálaigh CJ observed:

‘The constitutionality of a statute is, in many instances, determinable by a consideration and interpretation of the terms of the statute itself without reference to evidence as to their meaning and effect. Any matters necessary to elucidate its scope in such cases are matters of which the Court can take judicial notice. In the case of this Act⁴, however, the Court is considering a statute which uses scientific terminology, deals with a scientific procedure and requires scientific knowledge to comprehend the effect of its provisions. These are not matters which are presumed to be within the knowledge of the Court, and, accordingly, the unconstitutionality of the Act, if it be unconstitutional, cannot be determined except by reference to the particular evidence which is furnished in the case. Since evidence may differ from case to case as scientific knowledge may increase and views of scientists alter, the Court's determination cannot amount to more than a decision that on the evidence produced the plaintiff has, or has not, discharged the onus of demonstrating that the Act is unconstitutional. It is of importance that attention should be called at the outset to this aspect of the present case.’⁶

So far as the normative dimension is concerned, there is also an inevitable lack of closure. Constitutional norms relating to personal rights and other crucial criteria integral to the constitutional process are never stated finally by the courts, with no possibility of further reconsideration.

There are particular reasons why this should be the case in regard to the Irish Constitution, since Article 40.3 confers constitutional protection on the personal rights of the citizen without specifying expressly a list of these personal rights. The courts have thus a continuing role in articulating the nature and scope of these rights.⁶ It is therefore possible that, having made a determination that a particular statutory provision is constitutionally valid, the court may at some later time hold that it is not because in the meantime it has identified a particular, previously unspecified, personal right which renders the provision unconstitutional.⁷ At a more general and abstract level, the Irish Constitution contains a normative dynamism at an integral level. The Preamble provides that 'the people of Eire' adopt the Constitution, 'seeking to promote the common good, with due observance of Prudence, Justice and Charity, so that the dignity and freedom of the individual may be assured ...' In *McGee v Attorney General*⁸ Walsh J referred to this passage from the Preamble and observed:

'The judges must, therefore, as best they can from their training and their experience interpret these rights in accordance with their ideas of prudence, justice and charity. It is but natural that from time to time the prevailing ideas of these virtues may be conditioned by the passage of time; no interpretation of the Constitution is intended to be final for all time. It is given in the light of prevailing ideas and concepts.'⁹

Since *Ryan* was decided, several previously unspecified personal rights have been articulated by the courts, some of which clearly are relevant to the fluoridation issue. Moreover, at a more abstract juridical level, the courts have reassessed the basic function and precise role of law in defining the relationship between the State and its citizens. To an extent, of course, this reassessment is a response to, and reflection of, the social changes that have taken place in Ireland over the past thirty six years. Clearly there is a greater emphasis on the values of autonomy and privacy, with less desire on the part of the judiciary to police areas of private morality and personal choice.

It may be useful to identify and analyse the crucial legal concepts that are relevant to the contemporary determination of the fluoridation issue. They are the rights to bodily integrity, health, privacy, autonomy and dignity. None of these rights had received express judicial recognition prior to *Ryan*. Of course they are to some degree manifestations of a more general philosophy as to the role of the individual in society and the extent to which the forces of government may restrict individual life choices but, since they have been identified as distinct legal rights, they merit separate examination.

The right to bodily integrity

The natural starting point is the right to bodily integrity.

In *Ryan*, Kenny J understood this right to mean that:

'no mutilation of the body of any of its members maybe carried out on any citizen under authority of the law except for the good of the whole body and that no process which is or may, as a matter of probability, be dangerous or harmful to the life or health of the citizens or any of them may be imposed (in the sense of being may compulsory) by an Act of the Oireachtas.'¹⁰

He went on to state:

'If then the Act of 1960 imposes the consumption of fluoridated water on the citizens and if that is or may, as a matter of probability, be dangerous or harmful to the life or health of any of the citizens, the plaintiff's right to bodily integrity would be infringed and the legislation would be unconstitutional.'¹¹

Kenny J's understanding of the right to bodily integrity thus was expressed in negative rather than positive terms, involving two limitations on the relationship between external forces and the body of the citizen. The first was that 'no mutilation of the body or any of its members may be carried out on any citizen under authority of the law except for the good of the whole body'. Kenny J did not define 'mutilation'. It may be presumed that he understood it in the conventional sense of the cutting off a limb, removing a part of the body of badly damaging the body.¹² The precise parameters of this word in ordinary language are somewhat uncertain. The context of the intervention, the motive of the intervenor and the attitude or response of the person whose body is the subject of the intervention, as well as wide cultural norms, all play a role in conventional use of language in determining whether a characterisation of the intervention as 'a mutilation' will be appropriate. A sharp haircut would not be described as a mutilation, even when performed against the wishes of the person in question, because, of course, the hair will grow back again but also because interventions of this kind are culturally approved. The word 'mutilation' has no positive connotation. It represents an intervention that is *prima facie* bad news for the person whose body is involved. One suspects that communities where male circumcision (and, perhaps, female genital mutilation) are approved do not describe them in terms of 'mutilation', though, if pressed, they would have difficulty in denying that the word does include interventions of this character.

At all events, Kenny J considered that a mutilation of the body or one of its members could be justified if carried out 'for the good of the whole body'. Thus, for example, the amputation of a foot with gangrene would not violate a person's right to bodily integrity.

Whereas the removal of a part of the body is relatively easy to characterise as a mutilation (which may or may not be justified), it is far more difficult to determine the linguistic or legal parameters to the other meaning of mutilation, which involves serious damage to the body. Some cases are clear. A frenzied murderer who slashes at the facial features or other parts

of the body of the victim will be considered to have engaged in an act of mutilation but other contexts are less clear. A very heavily tattooed person will be regarded by many others as having been mutilated and if that person himself or herself did not consent to the tattooing process, he or she will join in that characterisation. Again, issues of cultural, consent and context will determine linguistic usage. The scar resulting from an appendectomy may be unsightly but the surgeon would be slow to admit that he or she had 'mutilated' the patient.

From a legal standpoint, this latter connotation of mutilation presents some difficulties, since it is not easy to relate the concept of 'the good of the whole body' to cases of this kind. Heavily tattooed or studded people may claim that they like their bodies in this condition but they might find it harder to convince a court that the process was designed to bring about, or did in fact bring about, the good of their whole bodies. Consent to the intervention does not necessarily equate with the good of the body of the person who consents.¹³

It is interesting to note the role of law in relation to the first element of Kenny J's definition of the right to bodily integrity: this is that no mutilation may be carried out 'under authority of the law' except for the good of the whole body. Kenny J here appears to be referring to the permitted range of legal authority that is consistent with the protection of the constitutional right of bodily integrity. It thus is capable of embracing not only actions by the State (or agents of the State) but also actions by private individuals, who have the authority of law for those actions. The reference to 'authority of the law' does not address, in express terms or, it may be argued, even impliedly, the question of the extent to which authority of the law can encompass mutilations to which the citizen does not consent. One can only give an impression of what Kenny J intended when he referred to authority of law but, reading the whole sentence, one has a sense that Kenny J countenanced favourably the possibility that such legal authority could include instances of non-consensual interventions.

Let us now examine the second element of Kenny J's definition of the right to bodily integrity. This is that:

'no process which is or may, as a matter of probability, be dangerous or harmful to the life or health of the citizens or any of them may be imposed (in the sense of being made compulsory) by an Act of the Oireachtas'.

The first point to note here to consider is that this element refers to the *compulsory* imposition by statute of a dangerous or harmful process: this would suggest that a statute which authorised a particular actor (whether an agent of the state or otherwise) to engage in a process that carried with it the risk of danger or harm to certain citizens but which involved no compulsory imposition on these citizens would not violate their constitutional right to bodily integrity. One might hesitate about the implications of this limitation. If, for example, a statute authorised an industrial enterprise to engage in a particular activity that polluted the environment and caused cancer to several hundred citizens, one might have thought it beyond argument that the injured citizens' right to bodily integrity had indeed been violated by such a legislative authorisation. Two responses may be canvassed. One is

that such a legislative authorisation to the polluting enterprise in fact involves a consequential compulsory imposition of a dangerous or harmful process on the citizens since they are obliged to suffer it by virtue of the legislative authorisation. This is perhaps straining Kenny J's language somewhat. The other response accepts that Kenny J did indeed intend to limit the second element of his definition to processes that are truly compulsory in the narrow sense of the term, and that he did so for a definite reason, which was to make it clear that violation of the right to bodily integrity, under the second element of the definition, requires this distinctive level of intrusion since otherwise the concept would flow over into the quite separate, though related concept of a constitutional right to health. In the example we have just mentioned, the injured citizens would indeed have a remedy - for violation of their right to *health*, which (it may be argued) is not limited in the scope of its protection to protection against compulsorily ordained processes. In *Ryan*, Kenny J was dealing with a compulsory process in the sense that citizens had to imbibe fluoridation as a matter of practical reality.

When the plaintiff appealed to the Supreme Court, her counsel argued that Kenny J's definition had been too narrow and contended that *any* interference with 'bodily constitution' was a violation of the right. The Supreme Court did not address this argument as it considered it unnecessary in the circumstances of the case:

'to define "bodily integrity" or the "right to the integrity of the person" or to consider to what degree and in what circumstances the State might interfere with the right, whether for the benefit of the individual concerned, the common good or by way of punishment. The Court is not pronouncing upon Mr. Justice Kenny's definition.'¹⁴

The law after *Ryan* was thus left in the somewhat unsatisfactory state that a right to bodily integrity had been recognised under Article 40.3 but its scope that had not been determined at the appellate level.

Later decisions have, fitfully and with no attempt at a comprehensive judicial analysis, gradually expanded upon the contours of this right.

*The State (C.) v Frawley*¹⁵ concerned a prisoner with a personality disorder of a sociopathic character and a propensity to attempt to escape from prison and to swallow objects that required medical operations to remove them. Managing his custody involved a regime that denied him much access to other prisoners or to material possessions (such as a radio) which contained parts which he might swallow. He challenged the lawfulness of his detention, arguing in essence, that his right to bodily integrity (*inter alia*) had been violated by the State's failure to provide a special psychiatric unit which could combine a custodial function with the provision of outlets for his physical capacity and aggressiveness. No such institution existed in Ireland. There were perhaps between six and twenty other people in Ireland suffering from a similar condition.

Finlay P accepted that the prisoner's argument that his right to bodily integrity imposed a duty to protect his health 'as well as is reasonably possible in all the circumstances of the case' was correct, though he preferred to express the right in negative terms rather than positive terms.

Finlay P stated:

'The right of bodily integrity as an unspecified constitutional right is clearly established by the decision of the Supreme Court in *Ryan v Attorney General*¹⁶, by which I am bound and which I accept. Even though it was there laid down in the context of a challenge to the constitutional validity of a statute of the Oireachtas which, it was alleged, forced an individual to use water containing an additive hazardous to health, I see no reason why the principle should not also operate to prevent an act or omission of the Executive which, without justification, would expose the health of a person to risk or danger.

When the Executive, in exercise of what I take to be its constitutional right and duty, imprisons an individual in pursuance of a lawful warrant of a court, then it seems to me to be a logical extension of the principle laid down in *Ryan's* case that it may not, without justification or necessity, expose the health of that person to risk or danger. To state ... that the Executive has a duty to protect the health of persons held in custody as well as is reasonably possible in all the circumstances of the case seems to me no more than to state in a positive manner the negative proposition which I have above accepted. Therefore, I am satisfied that such a proposition is sound in law.¹⁷

Finlay P went on to hold that the Executive had not failed in its duty on the basis that the State was not under the absolute duty to provide 'the best medical treatment irrespective of the circumstances'.¹⁸ It was "not the function of the Court to recommend to the Executive what is desirable or to fix the priorities of its health and welfare policy."¹⁹

The State (C.) v Frawley is of some importance to the fluoridation issue because Finlay P had no apparent difficulty in holding that the right to bodily integrity operates to prevent 'an act or omission of the Executive which, without justification would expose the health of a person to risk or danger.' This goes considerably further than Kenny J's formula, where, it will be recalled, the second element merely protected the citizen from the *imposition* of a process that may be harmful to health or life by *compulsion of an Act of the Oireachtas*. According to Finlay P, the Executive, in its *conduct* relative to its citizens, must not expose their health to risk or danger.

Clearly the Executive engages in many acts²⁰ which carry such a risk. The facts of the case were quite distinctive in that the prisoner, by virtue of his confinement, was in a position of compulsory exposure to the risk of dangerous acts by the Executive to an extent that is great than for most members of the public. Nothing that Finlay P said, however, indicates an intent on his part to limit the remit of this right to cases of this character.

It is worth noting that Finlay P's definition of the right to bodily integrity extends, not merely to acts, but also to *omissions* of the Executive which unjustifiably expose the health of a person to risk or danger. The prisoner in this case was essentially complaining about an omission to provide appropriate psychiatric facilities. It is one thing to penalise acts that are harmful to health or otherwise compromise a person's bodily integrity. It is another to complain about omissions that result in such a consequence. Traditionally the law has made a great distinction between harmful acts and omissions. Whereas harmful acts involve a wide net of liability, courts are generally very slow to stigmatise omissions as unlawful. They

predicate liability in these cases on the existence and breach of a specific duty on the part of the defendant.²¹ It is interesting to note that Finlay P seemed content to make no such restriction, instead embracing an unqualified principle of liability on the part of the Executive for any omission which, 'without justification', would expose a person's health to risk or danger. It has to be said that, in analysing whether the Executive's omission should be considered to have been 'without justification', Finlay P setup and then repudiated a standard - 'the best medical treatment irrespective of the circumstances' - which was plainly one that no court could adopt (and which does not appear to have been asserted by the prisoner) before adopting such a 'hands-off' stance on the part of the judiciary relative to priorities in health and welfare policy as, in effect, to render nugatory any question of judicial application of the criterion of Executive omission without justification.

In *G v An Bord Uchtála*²², where the validity of the consent of a mother to the placing of her child for adoption and the possibility of dispensing with the mother's consent to adoption were in issue, Henchy J in the Supreme Court addressed the scope of the right to bodily integrity for the first time at appellate level. He stated:

'As to the constitutional right to bodily integrity, such a right arises for recognition or enforcement only in circumstances which require that, in order to assure the dignity and freedom of the individual within the constitutional framework, he or she should be immune from a particular actual or threatened bodily injury or intrusion. No such question arises in this case. There is no suggestion that, whether the proposed adoption goes through or not, the child will suffer any bodily injury or intrusion.'²³

This consideration is summary and somewhat opaque. Nonetheless one can glean from it a willingness to address the right in terms of some substantive element in the relationship between the individual and threatened intrusions from outside, regardless of their provenance. To this extent Henchy J is reflecting Finlay P's perceptions of the right as one that restricts conduct as well as the mere enactment of legislation. In the instant case what was at issue was the effect of the making of an adoption order on the child. Undoubtedly such a process is of a legal character rather than capable of being described as a simple 'act', but Henchy J's brief description of the right did not appear to attach significance to this factor.

In *Norris v Attorney General*²⁴, where the plaintiff was attacking the consistency with the Constitution of statutory provisions rendering homosexual conduct criminal even when performed consensually by adults in private, one of his claims was that these provisions violated his right to bodily integrity. He made two arguments in this context. The first was that he had a right to use his body in the way that his inborn disposition suggested or required, so that he was entitled to engage in homosexual acts in private, and that the deprivation of this activity directly caused injury to his health 'through frustration and disorientation, or something similar.'²⁵ The second was that he suffered obloquy, was treated with contempt, might be left open to blackmail and intimidation and suffered various indignities, such as the opening of his mail, all of which affected his health and were greatly accentuated because homosexual activity was made criminal.

McWilliam J's analysis in the High Court, rejecting both arguments, is worth quoting in full:

'In considering these arguments and the statement of Mr. Justice Kenny in *Ryan's Case* it is well to remember that *Ryan's Case* was dealing with the compulsory consumption of a material which it was alleged to be dangerous or deleterious, whereas the present case is dealing with restrictions on the plaintiff engaging in certain activities which he wishes to pursue. There is a distinction between compelling a person to do something which he claims to be dangerous for his health and compelling a person to refrain from doing something, the indirect consequences of such restraint being to injure his health. It may be that the deprivation of the use by the plaintiff of his body in the way which his inborn disposition suggests or requires causes injury to his health, as he claims, but such result may arise from other lawful privations and, although the evidence is that the plaintiff has suffered in such a manner, it does not follow that this applies to all persons in his position and individual cases of hardship cannot invalidate statutes which can reasonably be considered by the legislature to be desirable for the attainment of the true social order and the preservation of the public order and morality mentioned in the Constitution.

The second part of the argument with regard to bodily integrity is of great relevance to the legislature in considering any alteration in or repeal of, the statutes However, a statute is not unconstitutional merely because it may create circumstances which give illdisposed persons an opportunity to commit unlawful acts, or may cause illinformed, prejudiced or uncharitable persons to be reinforced in their erroneous views.'

These distinctions are controversial. So far as the first is concerned it would seem to be refuted by the following example: a law prohibiting the ingestion of insulin would surely be unconstitutional and no less so than a law which required every citizen to ingest quantities of insulin appropriate only to those with a diabetic condition. Perhaps one should place special emphasis on McWilliam J's use of the words "indirect consequence". It seems that he perceived the injurious effects of the criminal prohibition of homosexual conduct as not being directly connected with the prohibition, seeking to achieve a purpose entirely unconnected with these possible effects which, it appears, McWilliam J did not regard as necessarily following from prohibition. So far as the second part of the plaintiff's argument is concerned, it is far from clear why a statutory provision which created circumstances that give illdisposed persons an opportunity to commit unlawful acts which damage another's health should necessarily be immune from invalidity. Naturally questions of foreseeability and individual responsibility need to be considered but today there is a greater judicial sensitivity to social discrimination and the responsibility of legislators to prevent its facilitation. This explains the basis of the Incitement to Hatred Act 1989, for example.

On appeal to the Supreme Court, the plaintiff's argument relating to bodily integrity was disposed of summarily. O'Higgins CJ (for the majority) stated:

'In my opinion this submission is not a sound one. If the legislation is otherwise valid and within the competence of the legislature to enact, it cannot be rendered inoperative merely because compliance with it by the plaintiff is difficult for, or harmful to, him due to his innate or congenital disposition. In this respect the exigencies of the common good must prevail.'

It has to be said that this is a remarkably unfeeling analysis which would be hard to justify in terms of principle. What the Chief Justice appears to be saying is that, once the court has established that the legislation is valid, *without having addressed its impact on a citizen's bodily integrity*, the court loses its capacity to reassess the issue of the validity of the legislation even on proof that the legislation, in conjunction with that citizen's innate or congenital disposition - a matter for which the citizen bears no moral responsibility - damages his bodily integrity. Expressed in these terms, the principle has to be rejected. A modified version, which had regard to the issue of the extent of the damage and contrasted it with proportionate regard for the common good, might perhaps be acceptable but that is not the version that the Chief Justice put forward.

*Walsh v Family Planning Services Ltd*²⁶, involves a curious judicial invocation of the right to bodily integrity. The plaintiff, who had suffered serious but most unusual ill-effects from a vasectomy carried out by the defendants, was awarded compensation by MacKenzie J in the High Court but the judgment was reversed on appeal. The Supreme Court judges were of the view that the award had been based on a technical trespass upon the plaintiff, since a doctor other than the doctor whom he had expected to perform the operation carried out the vasectomy. When one reads MacKenzie J's judgment closely, however, it seems that he awarded compensation on the basis that, while no negligence had been involved in the treatment and adequate disclosure of the risks associated with it had been made, nonetheless the plaintiff's 'constitutional right, that is an unspecified constitutional right to bodily integrity, ha[d] been violated.'²⁷

A crucial decision relating to the right to bodily integrity is *In re a Ward of Court (No 2)*.²⁸ In this case the Supreme Court, by a 4 to 1 majority, upheld Lynch J's order authorising the withdrawal of nutrition through a tube to the ward, a woman who had been in a near-PVS condition for very many years but who nonetheless retained some cognitive capacity, being able to differentiate between nursing staff and strangers.

In the High Court, counsel for the guardian *ad litem* referred to the case of a person subjected to torture who wished, in pursuance of his right to bodily integrity, to kill himself and submitted that he would have no right to do so. Counsel for the Attorney General submitted that, as all other fundamental rights, such as the right to bodily integrity or privacy or liberty, depend on the person claiming these rights being a living person, the right to life must always be given pre-eminence and not sacrificed in favour of these other fundamental rights.

Lynch J did not consider that these submissions were valid. He stated:

'Of course it should be so in the vast majority of cases but in the case mentioned by counsel for the guardian *ad litem*, I would think that if the torture was cruel enough and the prospects of relief remote enough, there must come a time when in the interests of privacy, dignity or autonomy, the victim would be within his rights in ending his own life if he had the means of doing so even before the enactment of the Criminal Law (Suicide) Act 1993. Less dramatic circumstances must also give a competent patient a right to refuse further medical or surgical treatment which he reasonably regards as excessively burdensome when weighed against the prospective benefits (if any) of the treatment even when such refusal will probably result in death'.

On appeal to the Supreme Court, several of the judges addressed the right to bodily integrity.

Hamilton CJ's analysis is less than fully clear. Under a heading which includes the words 'right to bodily integrity ...', the Chief Justice stated:

There is no doubt first that the ward, if she were mentally competent, had the right, if she so wished, to forgo [the] treatment or, at any time, to direct that it be withdrawn even though such withdrawal would result in her death.

This treatment involved a tube implanted surgically in her stomach through incisions in her abdominal wall and the provision of nutrition through the tube. Such treatment is intrusive, constitutes an interference with the integrity of her body and cannot be regarded as normal means of nourishment.

Her right to bodily integrity is one of the unenumerated personal rights recognised and protected by Article 40, s. 3 of the Constitution and was defined by Kenny in *Ryan v AG*, at page 313.²⁹

That represents Hamilton CJ's overt analysis of the right to bodily integrity. A few points may be made in its regard. First, by way of introduction, it may be noted that the Chief Justice's reference to Kenny J's definition appears to give it favour though it does not endorse it *expressis verbis*. Secondly, Hamilton CJ does not make a finding that the treatment constituted a *violation* of the ward's right to bodily integrity. His description was expressed in admittedly somewhat negative terms - the treatment was "intrusive" and constituted "an interference with the integrity of her body" - but it is surely significant that the Chief Justice held back from characterising it in terms of violation of a right.

O'Flaherty J identified an 'absolute right in a competent person to refuse medical treatment even if it leads to death.'³⁰ He quoted from a decision of a New Jersey Court³¹, to the effect that no right is more sacred than that of every individual to the possession and control of his or her own person, free from all interference by others, save by clear and unquestionable authority of law, O'Flaherty J commented:

'In American law this right is grounded both on common law as well as the constitutional right of self-determination (otherwise bodily integrity) as well as being regarded as a privacy right. Similarly, I believe that it would be correct to describe the right in our law as founded both on the common law as well as the constitutional rights of bodily integrity and privacy'.^{32,33}

The right of which O'Flaherty J is speaking is essentially that of autonomy, which, on his view, is founded on the right to bodily integrity (as well as the right of privacy and on common law). O'Flaherty J does not elucidate further on the contours of the right to bodily integrity but its capacity to act as the scaffolding (in conjunction with other rights) for the right of autonomy is worthy of note.

Denham J in her judgment observed that the requirement of consent to medical treatment was 'an aspect of a person's right to bodily integrity under Article 40.3...'³⁴ She noted that in

Ryan's Case the plaintiff had pursued her case against the State. Denham J added:

'However, the right to bodily integrity must be recognised by private individuals as well as the State'^{35,36}

Denham J went on to observe:

'It is not pertinent whether the treatment is ordinary or extraordinary medical treatment. Consent of the adult with capacity is necessary for either ordinary or extraordinary medical treatment.

However, the nature of the medical treatment here is pertinent to the ward's condition. The medical treatment is invasive. This results in a loss of bodily integrity and dignity. It removes control of self and control of bodily functions. When medical treatment is ingested, inhaled or applied then there is a voluntary co-operative effort by the patient and each time a voluntary effort occurs the patient reveals to their carers their continuing consent to treatment which invades the integrity of the body. When the treatment is administered by a tube or a needle, the element of co-operation by the patient is lost. Normally the benefits of such invasive treatment are clearly in a patient's best interest, but they are given to a patient in ways in which the individual has no control and are fundamentally different to non-invasive treatment.'³⁷

Later in her judgment, when discussing the right to privacy, Denham J quoted from the American decision of *In re Quinlan*³⁸ to the effect that '... the individual's right to privacy grows as the degree of bodily invasion increases.'

Clearly Denham J regarded the right to bodily integrity as enforceable, not merely against legislation or the acts of the Executive, but also against private individuals. This is in harmony with the approach favoured by MacKenzie J in *Walsh v Family Planning Services Ltd*³⁹, which had found no echo in the Supreme Court on appeal. The nature of a violation of bodily integrity has also expanded greatly from the somewhat narrow definition posited by Kenny J in *Ryan v Attorney General*. On Denham J's analysis, the contact does not have to be a mutilation or one that is damaging to health. Any contact to which the recipient does not consent will apparently violate his or her bodily integrity, even if the contact is entirely beneficial.

In *Brennan v Governor of Portlaoise Prison*⁴⁰ a prisoner challenged the legality of the conditions in which he was imprisoned at Portlaoise Prison, arguing that they constituted a danger to his health and well-being. One, of his complaints related to the policy of integrating prisoners with AIDS and HIV and Hepatitis B and C with other prisoners.

Rejecting this particular complaint, Budd J observed:

'while a blood test is a comparatively simple procedure nevertheless it poses difficulties in respect of the right to bodily integrity and confidentiality in respect of a person's condition. A policy of segregation of those with contagious diseases would necessarily involve some form of compulsory testing on prisoners. Government policy, based on expert advice, is in favour of the policy of integrating most of those suffering from AIDS, HIV and Hepatitis B and C. No doubt different considerations apply to TB or Hepatitis A.

While the applicant has expressed disquiet there would appear to be general acceptance in the prison community in respect of the policy of integration. In the circumstances it would be disproportionate to require all other prisoners to be subjected to compulsory testing in order to allay the apprehensions of the applicant.'

One would not wish to lay too much stress on the implications of Budd J's reference to the 'difficulties in respect of the right to bodily integrity' which a blood test might pose. It is nonetheless significant that the element of compulsion which such a test could involve was considered to be constitutionally problematic in spite of the benefits which such a test could obviously yield.

In *I O'T v B*⁴¹, the applicants argued that the right to bodily integrity (among other rights) required that they be informed of the identity of their mothers who, many years previously, had placed them for adoption. Their counsel submitted that a failure to allow them to do so would expose the health of each of them to the risk of physical and psychological damage. The physical risk arose from the possibility of marriage to a close relation, the psychological risk from the emotional consequences for them of being unable to ascertain the identity of their natural mothers.

The Supreme Court rejected the applicant's claim to be informed of their mothers' identity, largely on the ground that their mother's privacy interests trumped such entitlements. Hamilton CJ, dealing specifically with the arguments based on the right to bodily integrity, observed that the existence of a right to know the identity of their mother was:

'not dependent on the obligation to protect the child's right to bodily integrity or such rights as the child might enjoy in relation to the property of his or her natural mother but stems directly from the [natural and special] relationship [which exists between a mother and her child].'⁴²

Keane J disposed of the matter as follows:

'As to the submissions that the withholding from the applicants of the information in question constituted a risk to their bodily integrity (in everyday English, good health) and hence that the granting of the information was necessary in order to uphold the constitutional right in question, it is no doubt correct to say that, in a general sense, a risk to the physical health of a person can arise if he is not informed in every case of the identity of his natural mother. It is possible that such a person could marry or cohabit with a person closely related to them by blood with, it might be, harmful genetic consequences. Such consequences would, of course, affect, at most, the issue of such marriages and possibly not even them, depending on the present state of scientific knowledge on the topic. However, if it was to be laid down that the risk of this happening was of such an order that it necessitated recognition by the courts of an unenumerated right to know the identity of one's natural parents, it would render the system of legal adoption impossible. While a more flexible attitude is emerging today, on the part of both natural mothers and the adoptive parents, it remains the case that, in this as in other countries, anonymity is regarded as an essential feature of the process. Given the impossibility in practical terms of ensuring that children who, for whatever reason, have been brought up by persons other than their natural parents, are informed in every case

of the identity of their natural parents, it follows that some risk, in this as in so many other areas of life, of genetic damage to the issue may exist. The same may be said of the emotional damage on which the applicants also rely. In the light of the necessity for judicial restraint in the categorisation of new unenumerated rights, I am satisfied that it has not been established that there is a necessity to declare such a right on this ground alone.⁴³

The conflation here between the right to bodily integrity and the right to health is striking.

In *JS v CS (Otherwise CT)*⁴⁴, the applicant sought a decree of nullity of marriage on the basis (*inter alia*) of the respondent's mental incapacity. The Master of the High Court ordered that a psychiatric medical inspector should examine the respondent. The respondent argued that this infringed her right to bodily integrity (as well as her right to marital privacy).

Rejecting these arguments and specifically addressing the former of them, Budd J stated:

'It is clear that the Court will not lightly order an examination which is unpleasant, painful or potentially dangerous.⁴⁵ However, there is no evidence that the [respondent] would be put at risk by attending an interview. In any event, the petitioner's submission is that the order sought is for the appointment of the psychiatric inspector and that there is no mandatory requirement on a party to attend. Obviously, adverse comment may be made if a party refuses to attend, but this may well be subject to a reasonable explanation, for example, the recommendation of a person's treating psychiatrist in this respect. While I accept that a psychiatric examination may pry into a person's inner mind, I do not think that this necessarily constitutes an interference with a right to bodily integrity. If the [respondent] gives evidence, then she could be subjected to vigorous cross-examination in respect of her past mental state. Such a course of questioning could hardly be objected to on the basis that it infringed a right to bodily integrity. The Court has the right to hear relevant and admissible testimony from witnesses. In the light of the issues, the appointment of an independent medical inspector with psychiatric skills would appear to be reasonable.'

If one had to summarise the present scope of the right to bodily integrity in the light of these decisions, one would point to the gradual extension that has taken place over the years. The right is sometimes equiparated with the right to health. The alternative basis articulated by Kenny J, based on a concept of mutilation, has given way to a general right not to have physical contacts to which one does not consent. The right to bodily integrity is enforceable, not just against legislation which violates it, but also conduct (whether by way of act or omission) by the Executive or even private individuals. Clearly there must be limits to the right in terms of conduct impacting on it which is itself justifiable. The decisions have not yet produced a coherent analysis of the scope of justifiability in this context.

The right to health

As we have seen from the discussion of the right to bodily integrity, the courts, even from the start, have conflated the separate rights of bodily integrity and health. They are, however, logically distinct. One can easily envisage cases of infringement of the former right which do not involve any infringement of the latter. It is more difficult to conceive of cases involving infringement of the latter, but not the former, right. Perhaps cases involving psychiatric injury could be regarded as coming within this category but there is a respectable school of thought which would classify such an injury as corporeal in character.

At all events, the judicial analysis of the right to health, unconnected with the right to bodily integrity, is somewhat sparse.⁴⁶ One important case is *The State (Richardson) v Governor of Mountjoy Prison*⁴⁷. There a female prisoner complained about the conditions at the prison, arguing that they violated her constitutionally protected right to health. Barrington J held that the State had failed in its duty under the Constitution (and under the Prison Rules) "to protect the prosecutrix's health and to provide her with appropriate facilities to maintain proper standards of hygiene and cleanliness".

The right to privacy

The courts, in several decisions, have referred to a constitutionally protected right to privacy⁴⁸ and in a few decisions have invoked it as the basis of their determination of specific legal issues. The right still lacks conceptual coherence, however. This lack of coherence makes it difficult to anticipate the impact that the right to privacy will have in the context of the fluoridation issue.

Some of the matters relating to the right to privacy can be clearly stated. The right of marital privacy applies to married couples in regard to their access to contraceptives.⁴⁹ There is a right to privacy in one's telephone⁵⁰ and postal⁵¹ communications, for example.

The courts have addressed the subject in detail in two contexts, but their analysis has thrown little light on the provenance and contours of the right to privacy. In *Norris v Attorney General*⁵², the plaintiff unsuccessfully challenged the consistency of laws prohibiting homosexual conduct with the Constitution. He argued that there was a constitutional right to privacy which was violated by these laws. Prior to the *Norris* case, no court had recognised such a right. The Supreme Court, in *McGee v Attorney General*⁵³, however, had already recognised a right of marital privacy. The plaintiff's task was therefore to convince the Court to enlarge this right so as to transform it into a *generic* right to privacy. The plaintiff failed narrowly in this goal. Three of the five judges held against him. The language of O'Higgins CJ's judgment, for the majority, is elliptical but at no point did he concede, *expressis verbis*, that the plaintiff's asserted right to privacy had any constitutional status. The dissenting judges, Henchy and McCarthy JJ, clearly recognised the right to privacy. Henchy J stated that right "inheres in each citizen by virtue of his human personality"⁵⁴ He discerned, amongst the citizen's personal rights,

'a complex of rights which vary in nature, purpose and range (each necessarily being a

facet of citizen's core of individuality within the constitutional order) and which may be compendiously referred to as the right of privacy.⁵⁵

Henchy J went on to observe that, as well as the right to marital privacy recognised in McGee's Case, there were:

'many other aspects of the right of privacy some yet to be given judicial recognition. It is unnecessary for the purpose of this case to explore them. It is sufficient to say that they would all appear to fall within a secluded area of activity or non-activity which may be claimed as necessary for the expression of an individual personality, for purposes not always necessarily moral or commendable but meriting recognition in circumstances which do not engender considerations such as State security, public order, or morality, or other essential components of the common good.'⁵⁶

Later in his judgment, Henchy J indicated that he regarded the right of privacy as encompassing 'the expression of those primal urges, functions and aspirations which are integral to the human condition of certain kinds of homosexuals'.⁵⁷

McCarthy J proceeded on the basis that '[t]he right to privacy is not in issue.'⁵⁸ He sought to resolve the question of the *extent* of the right. The picture that emerges from his judgment is of a right of the broadest generality with no clearly distinctive features.

The Supreme Court returned to the subject in *In re a Ward of Court (No. 2)*⁵⁹, the case concerning the withdrawal of nutrition through a tube from a woman who had been for many years in a persistent or permanent vegetative state but who nonetheless retained a minimal cognitive capacity.

Hamilton CJ stated:

'The loss by an individual of his or her mental capacity does not result in any diminution of his or her personal rights recognised by the Constitution, including the right to life, the right to bodily integrity, the right to privacy, including self-determination, and the right to refuse medical care or treatment.

The ward is entitled to have all these rights respected, defended, vindicated and protected from unjust attack and they are in no way lessened or diminished by reason of her incapacity.'

O'Flaherty J also identified the right of a competent person to refuse medical treatment 'even if it leads to death' as 'founded both on common law as well as the constitutional rights of bodily integrity and privacy.'

Neither Hamilton CJ nor O'Flaherty J developed the analysis of the nature of the constitutional right to privacy beyond a formal recognition of its existence. They both referred to judicial precedent⁶¹ that was far removed from the stark context of authorising a course of action that was intended to have the result of terminating a person's life.

Denham J's discussion of privacy is far more radical. She observed that:

'[p]art of the right to privacy is the giving or refusing of consent to medical treatment. Merely because medical treatment becomes necessary to sustain life does not mean that the right to privacy is lost, neither is the right lost by a person becoming insentient. Nor is the right lost if a person becomes insentient and needs medical treatment to sustain life and is care for by people who can and wish to continue taking care of the person. Simply it means that the right may be exercised by a different process. The individual retains their personal rights.

The right to privacy is not absolute. It has balanced against the State's duty to protect and vindicate life. However, ... the individual's right to privacy grows as the degree of bodily invasion increases.

The increasing personal right to privacy is in such a situation inconsistent with the defence and vindication of life being as far as practicable and the protection being as best it may.

A constituent of the right of privacy is the right to die naturally, with dignity and with minimum suffering. This right is not lost to a person if they become incapacitated or insentient.'

Denham J made it clear that in applying the 'best interests' test, the totality of the ward's situation, including her constitutional right to privacy, autonomy, "dignity in life" and 'dignity in death', had to be considered.

Denham J's analysis of the character of the constitutional right to privacy is fuller than that of her judicial colleagues. What emerges is a strongly individualist norm in which choices affecting oneself must be respected by others even where this has damaging, or even lethal, consequences for oneself. The influence of Mill and Hart on this philosophy is easy to discern.⁶¹

On this approach, the actions of the medical and nursing staff in seeking to provide nourishment to the ward by means of the tube are to be regarded as a highly invasive intrusion on the ward's bodily integrity. The ward's dignity - an aspect of privacy on Denham J's analysis - was compromised by her becoming "a passive prisoner of medical technology.'

The contours of the constitutional right to privacy are thus hard to discern. Beginning with aspects of conduct to which the conventional linguistic description of 'private' could comfortably be attached, the courts have been moving to a more abstract notion of a realm of decision-making which is outside the legitimate purview of State control. Such decision-making is not necessarily private in the conventional linguistic sense. It is closer to the concept of autonomy (or self-determination), to which we now turn.

The right to autonomy

The courts in recent years have placed a strong emphasis on autonomy as a constitutionally protected value. It is, of course, inherent in the right to personal liberty, protected by Article 40.4.10, the right to due process recognised by Article 38.10 and the several personal rights protected by Article 40.2 and 3. Moreover, the Preamble, as we have seen, sets as a constitutional goal the assurance of 'the dignity and freedom of the individual'. The right of citizens to choose how they shall act or, as the case may be, decline to act, underlines such decisions as *Walsh v Family Planning Services Ltd*⁶² and, of course, the *Ward of Court Case*⁶³. In the *Ward of Court Case* Hamilton CJ referred to the 'right to ... self determination'.⁶⁴ O'Flaherty J spoke in identical terms.⁶⁵

Denham J made a number of important observations on the subject. She stated:

'Medical treatment may not be given to an adult person of full capacity without his or her consent. There are a few rare exceptions to this, e.g., in regard to contagious diseases or in a medical emergency where the patient is unable to communicate. The right arises out of civil, criminal and constitutional law. If medical treatment is given without consent it may be trespass against the person in civil law, a battery in criminal law, and a breach of the individual's constitutional rights. The consent which is given by an adult of full capacity is a matter of choice. It is not necessarily a decision based on medical considerations. Thus, medical treatment may be refused for other than medical reasons, or reasons most citizens would regard as rational, but the person of full age and capacity may make the decision for their own reasons.'⁶⁶

Later in her judgment, under the heading, Right of Choice, Denham J observed:

'As part and parcel of their constitutional rights, a patient has a right to choose whether she will or will not accept medical treatment. This concept is the requirement of consent to medical treatment seen from another aspect.'⁶⁷

She listed several factors which the court should take into consideration in determining where the ward's best interests lay. One of these was '[t]he ward's constitutional right to ...Autonomy'.⁶⁸

The Right to Dignity

Dignity as a human attribute has in recent years generated judicial interest to the extent that a constitutionally protect right to dignity has been recognised. The Constitution refers to the subject in the Preamble where the 'people of Eire', 'seeking to promote the common good, with due observance to Prudence, Justice and Charity, so that the dignity and freedom of the individual may be assured', adopt the Constitution. The Preamble does not enlarge on the nature of 'the dignity and freedom of the individual'.

In *McGee v Attorney General*⁶⁹ Henchy J invoked the Preamble when analysing the validity of legislation prohibiting the interpretation or sale of contraceptives. This had the effect of 'condemn[ing] the plaintiff and her husband to a way of life which, at best, will be fraught

with worry, tension and uncertainty that cannot but adversely affect their lives and, at worst, will result in an unwanted pregnancy causing death or serious illness with the obvious tragic consequences to the lives of her husband and young children. And this in the context of a Constitution which in its preamble proclaims as one of its aims the dignity and freedom of the individual...'

Other judges have referred to this aspect of the Preamble. In *In re Clarke*⁷⁰, O'Byrne J, delivering the judgment of the Supreme Court in an unsuccessful constitutional challenge to the validity of aspects of the Mental Treatment Act 1945, stated:

'The impugned legislation is of a paternal character, clearly intended for the care and custody of persons suspected to be suffering from mental infirmity and for the safety and well-being of the public generally. The existence of mental infirmity is too widespread to be overlooked and was, no doubt, present to the minds of the draughtsmen when it was proclaimed in Article 40.1 of the Constitution that, though all citizens, as human beings, are to be held equal before the law, the State may nevertheless, in its enactments, have due regard to differences of capacity, physical and moral, and of social function. We do not see how the common good would be promoted or the dignity and freedom of the individual assured by allowing persons alleged to be suffering from such infirmity to remain at large to the possible danger of themselves and others.'

In *Buckley v Attorney General*⁷¹, O'Byrne J, again delivering the judgment of the Supreme Court, quoted the relevant passage from the Preamble and stated:

'These most laudable objects seem to us to inform the various Articles of the Constitution, and we are of opinion that, so far as possible, the Constitution should be so construed as to give them life and reality.'

In *The State (Healy v Donoghue)*⁷², Gannon J in the High Court observed:

'The promotion of the common good so that the dignity and freedom of the individual may be assured, being the objective stated in the Preamble to the Constitution, is as much a function and responsibility of the judicial organ of the State as of the legislature or executive.'

On appeal to the Supreme Court, O'Higgins CJ quoted from what Walsh J had said in *McGee v Attorney General*⁷³ to the effect that no interpretation of the Constitution is intended to be final for all time. The Chief Justice was of the view that the Preamble:

'makes it clear that rights given by the Constitution must be considered in accordance with concepts of prudence, justice and charity which may gradually change or develop as society changes and develops, and which fall to be interpreted from time to time in accordance with prevailing ideas. The Preamble envisages a Constitution which can absorb or be adapted to such changes.'⁷⁴

It will be recalled that in *G. v An Bord Uchtála*⁷⁵ Henchy J, referred to the adoption of a child linked the Preamble's reference to the dignity and freedom of the individual with the right to bodily integrity first recognised in *Ryan v Attorney General*⁷⁶. Henchy J stated:

'As to a constitutional right to bodily integrity, such a right arises for judicial recognition

or enforcement only in circumstances which require that, in order to assure the dignity and freedom of the individual within the constitutional framework, he or she should be held immune from a particular actual or threatened bodily injury or intrusion. No such question arises in this case. There is no suggestion that, whether the proposed adoption goes through or not, the child will suffer any bodily injury or intrusion.'

In *Garvey v Ireland*⁷⁷ the Preamble's reference to dignity was seen as having relevance to the manner in which the Commissioner of the Garda Síochána was removed from office by the Government. Henchy J stated:

'An office such as this, which provides its holder with his livelihood, and in which he may reasonably hope to qualify for honourable retirement, is such an integral part of what goes to make up his dignity and freedom that his removal from it should have attached to it at least the justification of a stated and examinable reason.'⁷⁸

In *Norris v Attorney General*⁷⁹ Henchy J referred to the Preamble and other provisions of the Constitution and observed that:

'There is necessarily given to the citizen, within the required social, political and moral framework, such as a range of personal freedoms and immunities as are necessary to ensure his dignity and freedom as an individual in the type of society envisaged. The essence of those rights is that they inhere in the individual personality of the citizen in his capacity as a vital human component of the social, political and moral order polited by the Constitution.

Amongst those basic personal rights is a complex of rights which vary in nature, purpose and range (each necessarily being a fact of the citizen's core of individuality within the constitutional order) and which may be compendiously referred to as the right of privacy.'

The fact that homosexual conduct was contrary to the standards of morality advocated by the Christian Churches in the State should, in Henchy J's view, not be treated as a guiding consideration:

'What are known as the seven deadly sins are authorised as immoral by all the Christian Churches, and it would have to be conceded that they are capable, in different degrees and in certain contexts, of undermining vital aspects of the common good. Yet it would be neither constitutionally permissible nor otherwise desirable to seek by criminal sanctions to legislate their commission out of existence in all possible circumstances. To do so would upset the necessary balance which the Constitution posits between the common good and the dignity and freedom of the individual. What is deemed necessary to his dignity and freedom by one man may be abhorred by another as an exercise in immorality. The pluralism necessary for the preservation of constitutional requirements in the Christian democratic State envisaged by the Constitution means that the sanctions of the criminal law may be attached to immoral acts only when the common good requires their proscription as crimes.'

McCarthy J in the same case stated that he:

'would uphold the view that the unenumerated rights derive from the human personality and that the actions of the State in respect of such rights must be informed by the proud

objective of the people as declared in the preamble 'seeking to promote the common good, with due observance of prudence, justice and charity, so that the dignity and freedom of the individual may be assured, true social order attained, the unity of our country restored, and concord established with other nations.' The dignity and freedom of the individual occupy a prominent place in these objectives and are not declared to be subject to any particular exigencies but as forming part of the promotion of the common good.⁸⁰

In *Kennedy v Ireland*⁸¹ Hamilton P observed:

'The nature of the right to privacy must be such as to ensure the dignity and freedom of an individual in the type of society envisaged by the Constitution, rarely, a sovereign, independent and democratic society.

The dignity and freedom of an individual in a democratic society cannot be ensured if his communications of a private nature, be they written or telephonic, are deliberately, consciously and unjustifiably intruded upon and interfered with."

In *Attorney General v X*⁸² O'Flaherty J was of the view that an injunction against travelling abroad to have an abortion was not permissible under the Constitution:

'Such a regime is impossible to reconcile with a Constitution one of the primary objects of which, as stated in its Preamble, is to assure the dignity and freedom of the individual.'

In *Molyneux v Ireland*⁸³ the plaintiff, who was charged with assault under section 28 of the Dublin Police Act 1842, argued that the Act was inconsistent with the Constitution on the basis that it violated the guarantee of equal treatment given by Article 40.1. Costello P rejected this argument as being:

'Based on a misunderstanding of the Article The preamble to the Constitution declares that by enacting it the people of Ireland were, *inter alia*, seeking to promote the common good so that the 'dignity and freedom' of the individual might be assured, and it required by Article 40.1 that all citizens 'as human persons' should be held equal before the law. The concepts thereby enshrined are ones which, quite literally, are universally recognised. The 1948 UN Declaration of Human Rights refers in its preamble to 'the inherent dignity of all members of the human family' and declares in Article 1 that 'all human beings are born free and equal in dignity and rights'. Innumerable laws are enacted in every state which treat differently one group or category of persons from other groups or categories of persons by imposing deterrents or conferring benefits on one group or category and not on others. Every law which so provides does not of course breach the concept contained in Article 40.1 of the Constitution or Article 1 of the Universal Declaration The Supreme Court has explained why. The guarantee in the Constitution is not a guarantee of absolute equality for all citizens in all circumstances, but is a guarantee of equality as human persons relating to their dignity as human beings and a guarantee against inequalities based on the assumption that some individuals because of their human attributes, ethnic, racial, social or religious background are to be treated as inferior or the superior of other individuals in the community.'

This perception of dignity as inhering in the human person rather than being contingent on

particular external realities is undoubtedly in harmony with the natural law philosophy grounding the Constitution.

In the *Ward of Court* Case, dignity was treated in a radically new way by Denham J. For the first time she identified a *right* to dignity, in contrast to the perception of dignity as a quality inhering in the human person. She stated:

'An unspecified right under the Constitution to (sic) all persons as human persons is dignity - to be treated with dignity. Such right is not lost by illness or accident. As long as a person is alive they have this right. Thus, the ward in this case has a right to dignity. Decision-making in relation to medical treatment is an aspect of the right to privacy; however, a component in the decision may relate to personal dignity. Is the ward, as described by Brennan J in his dissenting judgment in *Cruzan v Director, Missouri Department of Health*⁸⁴, "a passive prisoner of medical technology"? If that be so, is it in keeping with her right as a human person to dignity? Just as 'the individual's right to privacy grows as the degree of bodily invasion increases'⁸⁵, so too the dignity of a person is progressively diminished by increasingly invasive medicine.'⁸⁶

Denham J considered that a range of factors had to be taken into account by the court in determining where the best interests of the ward lay. These included the wards 'constitutional right to ... (e) Dignity in life. (f) Dignity in death.'⁸⁷

Denham J did not seek to analyse the constitutional 'right to dignity' further. So far as one can see from her brief description of the right, she appeared to regard a person's dignity as being capable of being diminished by invasive medicine; the greater the degree of invasiveness the greater the consequent diminution of the person's dignity. Dignity would appear thus to be determined by reference to the extent to which the values of autonomy and privacy are compromised by external factors. Dignity, on this view, is not essentially an inherent characteristic of the person.

In the same sense O'Flaherty J described the ward's life as 'technically ... life, but life without purpose, meaning or dignity.'⁸⁸ Like Denham J, O'Flaherty J did not regard dignity as a value inhering in the person but rather as a quality that can depart from the person by virtue of external circumstances.

The implications of judicial recognition of the rights on the fluoridation issue

We now must consider the implications of the judicial recognition of the rights of health, privacy, autonomy and dignity, and the judicial development since *Ryan v Attorney General* of the right to bodily integrity on the fluoridation issue. If the constitutional validity of the fluoridation of public water supplies were to be challenged in new litigation, then it is certain that, as well as modern scientific evidence being adduced, the plaintiff's lawyers would invoke this panoply of individual-centred rights as a counterpoint to the paternalistic and communitarian policies underlying the legislation.

Undoubtedly the common good must be balanced against individual rights. This was plainly the view of the majority in the *Norris* case, but, viewed from the perspective of 2001, the

emphasis on the common good seems more difficult to reconcile with the values of privacy and autonomy. It is worth noting also that, in the *Ward of Court* Case, Denham J interpreted the common good as being permeated by individualist values. Under the heading, Common Good, she stated:

'In analysing the right to life, attention must be given to the person's right to life, privacy, autonomy and bodily integrity. Also the common good, in the protection of life, must be considered. It is an area where the two interests may appear to conflict.

The common good is achieved by the protection of life within the community. However, we recognise that a competent adult may decide that they do not consent to medical treatment. The State's respect for the life of the person encompasses the right of the person to hold views such that, for religious and other reasons, they refuse medical treatment. In the acceptance of the person's decision, their life is respected ...

The primary constitutional concept is to protect life within the community. The State has an interest in the moral aspect of society - for the common good. But, balanced against that is the person's right to life - which encompasses a right to die naturally and in the privacy of the family and with the minimum suffering.'⁸⁹

It is worth recalling also that the Preamble to the Constitution sees no conflict between the common good and individualist norms. On the contrary, it posits the promotion of the common good, mediated by due observance of Prudence, Justice and Charity, as a precondition of the assurance of the dignity and freedom of the individual.

Let us first summarise the impact of the personal rights which we have been discussing on the fluoridation issue. An individual has the right of autonomy or self-determination, to choose what contacts he or she engages in. The right to bodily integrity also gives the individual to set down the parameters of such contacts. The right to privacy is somewhat more incoherent but carries with it the notion that an individual is entitled to live life in accordance with his or her life-plan and values, save to the extent that this trenches illegitimately on the rights of others. The right to dignity is still more uncertain in its scope. The judicial view that dignity can be compromised by external factors suggests that the compulsory intrusion of a foreign substance into the body might be regarded as infringing the right to dignity.

Looking at these several rights in conjunction it might be argued that, if an individual is entitled to refuse medical treatment, even where that decision is 'not necessarily ... based on medical considerations,'⁹⁰ it would be odd if the individual should be obliged by law to subject himself or herself to the incursion within his or her body of a substance which he or she does not wish to imbibe. On this view, the Executive is, of course, entitled to advocate a particular life-style which is a healthy one, judged against certain premises, such as longevity and the absence of disease or bodily impairment, but the Executive is not constitutionally permitted to force this life-style on its citizens, either through laws requiring them to act in a particular way or through laws which result, in practice, in their being unable to avoid living in accordance with that life-style model, either through constriction of

choice or the actual imposition of the policy physically by way of incursion of the beneficial process into the bodies of citizens.

In responding to this argument, the courts have several points which they could credibly say represent the limit to permissible action by the Executive. They could, for example, hold that the Executive is perfectly entitled, not only to advocate a particular life-style, but by its policies to narrow choices so that this life-style, for practical purposes, becomes the only one available to citizens in particular areas of their lives. For example, the law banning marijuana is not unconstitutional on account of its interference with choice and a law banning the sale or consumption of cigarettes would also appear to withstand constitutional challenge on this ground. Similarly, a law that adopted a differential taxation policy to make certain life-style choices, stigmatised on health grounds, difficult or, in practice, impossible to engage in would not be constitutional.

The problem with fluoridation in the water supplies is that it involves the non-consensual incursion of a substance into the body. The courts could take one of several approaches to this issue. The most radical would, of course, be to hold that all non-consensual incursions are unconstitutional, on the basis that they violate the rights to bodily integrity, privacy, autonomy and dignity (or any one or more of these rights).

The next stopping point would be to distinguish between different incursions and to permit those that might be regarded as 'natural'. So, for example, if the purification of water involves the introduction of a particular substance into the water supply, the court could characterise the purified water as including nothing other than natural ingredients, in respect of the imbibing of which no citizen could legitimately complain. It is interesting that, in *Ryan v Attorney General*⁹¹, this is how the Supreme Court appears to have characterised the process of fluoridation:

'The Court does not accept that the fluoridation of water is, or can be described as, the mass medication or mass administration of "drugs" through water. It has already been pointed out that the fluoridation is a process by which an element which naturally occurs in water is, in the case of a particular water supply, raised to a level of concentration at which it is found in wholesome water and that the fluoride ions thus added are not different in nature or action from the fluoride ions occurring naturally in water. This matter was examined in detail by the Commission set up by the Government of New Zealand to enquire into "the Desirability or otherwise of the Fluoridation of Public Water Supplies" and the conclusion was reached that 'fluoride is not a drug but a nutrient and fluoridation is a process of food fortification'. It is, in the opinion of the Court a misuse of words to refer to this process as mass medication or mass administration of drugs.'

It is far from clear that a court today would adopt the same characterisation. If the process were to be classed as a form of mass medication, a question would arise as to the relationship between medication and medical treatment. Characterisation is important in this context because, if a particular process is characterised as falling under the general umbrella of medical treatment, then it will be treated distinctively for legal purposes. As the *Ward of Court* Case makes plain, a person has the constitutional right to refuse medical

treatment. If there is a right to refuse medical treatment, it is hard to see how there is nonetheless an obligation to submit to legislatively authorised State action that constitutes medical treatment. In the *Ward of Court* case, the process of feeding the ward through a tube was characterised as medical treatment. It is a good deal less clear that the fluoridation of the water supplies is medical treatment. It admittedly has an intended health benefit and medical treatment can be prophylactic in character but a court might nonetheless balk at describing the process as medical treatment.

Another stopping point that a court might favour concentrates on the legitimacy of public health policies. In essence, the Government may be seen as having, not merely an entitlement, but also the obligation to protect the health of the citizens. A necessary element of this duty is making rules which curtail the rights of citizens, to a greater or a lesser degree, in order to accomplish these public health goals. A question of proportionality thus may be considered to arise. Just as public health will not justify *all* such curtailments of rights, equally a public health goal will serve to justify *some* curtailments, provided they are rational and proportionate.

In *Ryan v Attorney General* the Supreme Court adopted this approach. Ó Dálaigh CJ, for the Court stated:

'It is beyond question that dental care in children has become a national problem in this State.... It can result not merely in damage to the teeth themselves but, through the existence of decayed or decaying teeth, may be injurious to general health. The State is organised for the common welfare of all its citizens and in a society arising from man's nature. Apart from particular expressed limitations contained in the Constitution, the Oireachtas may not enact legislation depriving citizens of their essential rights as human persons or its members of the family. The State has the duty of protecting the citizens from damages to health in a manner not incompatible or inconsistent with the rights of those citizens as human persons.

Dental caries is no new thing. It has adversely affected generation after generation and will continue to do so if measures are not taken. This constitutes the type of danger from which the State has not merely the right but the duty to protect its citizens. To deal with the problem the Oireachtas has chosen a method, namely, the fluoridation of the public water supply. The plaintiff has failed to refute the evidence that this is not only the most effective method but is indeed the only effective method. The method undoubtedly does result in a minimal interference with the constitution of the body, but such interference is not one which in any way impairs the functions of the body or, to any extent discernible by the ordinary persons, its appearance.¹⁹²

It is highly likely that the courts, with some modifications as to scientific and social factors, would take the same view of the legislation today. When one examines the judicial analysis of the several individualist rights that we have been describing, this analysis rarely takes place in a context where the right is in opposition to a desirable social policy being effectuated by the State. In *Norris*, where the social policy underlying the legislative prohibitions found favour with the Supreme Court, the social policy defeated the asserted individualistic right. In the *Ward of Court* case, the individualistic rights were seen by the

Supreme Court, not to conflict potentially with any social policy, but rather with another individualistic right - the right to life.

We now must consider an important High Court decision which should occasion much reflection. In *North Western Health Board v HW and CW*⁹³, the parents of an infant refused to give their permission to a nurse employed by the health board to carry out the PKU test on their child. They did so on the basis that the process involved invasive measures. They declared that it was their strong religious belief that "nobody should be allowed to injure anybody else". They were happy to have their child tested by non-invasive means for the several disabilities that the PKU test could uncover. The Health Board sought injunctions requiring the parents to give their consent to the PKU test.

McCracken J refused to grant the injunctions. He was guided largely by Article 42.5 of the Constitution which authorised action by the State interfering with parental rights only in exceptional cases of parental failure. Moreover, Article 41 placed the family in a special constitutional position. In the instant case McCracken J was satisfied that the merits of the case, medically speaking, were in favour of carrying out the test, but this was not in itself a reason for granting the injunctions. Parents were entitled to come to wrong decisions regarding their children's welfare in a wide variety of areas, not merely in the context of medical decision-making. Provided the failure was not of an exceptional character, it was not right for the State's view always to prevail. For it to do so would involve a rapid movement towards a Brave New World where the State always knows best. In an important passage, McCracken J observed that the State's policy for inoculations and vaccinations of children did not involve compulsion; in these instances the case for compulsion was far stronger than in respect of the PKU test.

McCracken J distinguished *Ryan v Attorney General* on the basis that the plaintiff in that case had sought to prevent the entire community from having the benefits of fluoridation whereas in the instant case the parents were seeking only to prevent their child from the process.

The *North Western Health Board* case gives pause for thought. It raises the alarming question as to whether a public health policy involving compulsion (in the way that fluoridation in the water supplies forces the material into the bodies of unwilling recipients) could be regarded as unconstitutional relative to Article 41 and 42 while not unconstitutional relative to the personal rights of the citizen protected in Article 40. In other words is there a zone of parental decision-making which may not be interfered with by such a public health policy? One suspects that the courts would - and should - be very reluctant to come to that conclusion.

To summarise the legal position in relation to the fluoridation issue: Ryan's case is not a guarantee that the courts would today make an identical holding of fact or law. I am not competent to address the scientific questions involved or to predict how the courts would determine them. If, of course, a court were to conclude that fluoridation is harmful, then inevitably the legislation would be held unconstitutional. If, however, a court were to conclude that fluoridation is not harmful but beneficial, that does not necessarily mean that

the legislation would be upheld since it could still be considered to infringe any one or more of the constitutionally-protected rights which have been analysed in this paper. It is the personal view of the author, however, that the courts would be very reluctant, and therefore very unlikely, to come to such a conclusion.

- 1 [1965] IR 294.
- 2 (1978) 14 DR 31, E Comm HR. See further van Dijk & van Hoof, *Theory and Practice of the European Convention on Human Rights* (3rd ed, 1998) Chapter 7, esp at pp 296 ff.
- 3 (1965) IR, at 343.
- 4 The Health (Flouridation of Water Supplies) Act 1960, and the regulations made under it: the Flouridation of Water Supplies (Dublin) Regulations 1962 (SI 1962, No 75).
- 5 The courts in other contexts where a scientific issue is raised have also make it plain that they determine the issue on the basis of the evidence adduced in the particular case and that the determination does not purport to amount to a resolution of the issue within the scientific order: see, eg *Best v Wellcome*.
- 6 *Ryan's Case* was crucial in establishing for the first time that the courts have this role.
- 7 We need not here address the particular difficulties that surround a finding by the Supreme Court, under the Article 26 procedure, that a Bill referred to it by the President is constitutionally valid.
- 8 (1974) 284, at 319.
- 9 See also *The State (Healy) v Donoghue* [1976] IR 326, at 347 (Sup Ct, per O'Higgins CJ), *Attorney General v X* [1992] 1 IR1 (Sup Ct, per Finlay CJ); cf Byrne & Binchy, *Annual Review of Irish Law* 1992.
- 10 [1965] IR, at 313-314.
- 11 *Id.*, at 314.
- 12 Chambers Pocket Dictionary, p 484 (1988 ed).
- 13 Cf. *R v Brown (Anthony)* [1994] 1 AC 212, distinguished in *R v Wilson* [1997] QB 47. See also *R v Emmett, CA (Crim Div)*, 18 June 1999, *R v McIntosh*, Victoria Sup Ct., 3 September 1999.
- 14 [1965] IR, at 345.
- 15 [1976] IR 365.
- 16 *Supra*.
- 17 *Id.*
- 18 *Id.*
- 19 *Id.*
- 20 The position relating to omissions will be addressed presently.
- 21 See McMahon & Binchy, *Irish Law of Torts* (3rd ed, 2000), Chapter 8. It is worth noting that the decision of the European Court of Human Rights in *Osman v United Kingdom* [1999] 1 FLR 193 has had an important effect in reducing the circumstances in which culpable inaction will not engender liability.
- 22 [[1980] IR 32.
- 23 *Id.*
- 24 [1984] IR 36.
- 25 *Id.*
- 26 [1992] 1 IR 496.

- 27 *Id.* See further McMahon & Binchy, *op cit*, paras 1485 ff.
- 28 [1996] 2 IR 79.
- 29 [1996] 2 IR, at 124-125.
- 30 *Id.*, at 129.
- 31 *In re Conroy* 98 NJ 321 (1985), echoing what had been said in *Union Pacific Ry Co v Botsford*, 141 US 250 (1891).
- 32 Citing *Ryan v Attorney General* [1965] IR 294 and *Kennedy v Ireland* [1987] IR 587.
- 33 [1996] 2 IR, at 129-130.
- 34 *Id.*, at 156.
- 35 Citing *The People (DPP) v JT*, 3 Frewen 141 at 158 (1988).
- 36 *Supra*.
- 37 [1996] 2 IR at 158.
- 38 355 A 2d 647 (1976).
- 39 *Supra*.
- 40 High Ct, 3 September 1998.
- 41 [1998] 2 IR.
- 42 *Id.*
- 43 *Id.*
- 44 High Ct, 14 October 1996.
- 45 Citing *Aspinall v Sterling Mausell*, [1981] 3 All ER 866 and *Prescott v Bulldog Toole* [1981] 3 All ER 869.
- 46 See, e.g., *Colmey v Pinewood Developments Ltd*, High Ct, 13 October 1994, *The State (Richardson) v Governor of Mounjoy Prison*, High Ct, 28 March 1980, *Heeney v Dublin Corporation*, Supreme Ct, 17 August 1988, *Brennan v Governor of Portlaoise Prison*, High Ct, 3 September 1998.
- 47 High Ct 28 March 1980.
- 48 See the Law Reform Commission's Consultation Paper on Privacy: Surveillance and the Interception of Communications (1996).
- 49 *McGee v Attorney General* [1974] IR 284.
- 50 *Kennedy v Ireland* [1987] IR 587.
- 51 *Kearney v Ireland* [1986] IR 116.
- 52 [1984] IR 36.
- 53 *Supra*
- 54 [1984] IR, 71.
- 55 *Id.*, at 71-72.
- 56 *Id.*, at 72.
- 57 *Id.*, at 79.
- 58 *Id.*, at 101.
- 59 *Supra*.
- 60 *Ryan v Attorney General* [1965] IR 294; *Kennedy v Ireland* [1987] IR 587.
- 61 See Kelly, *A Short History of Western Legal Theory* (1992) pp 339-340, 443-447.
- 62 [1992] 1 IR 486.
- 63 [1996] 2 IR 79.
- 64 *Id.*, at 124. This appeared as a heading ("*Right to bodily integrity, privacy and self-determination*") rather than as part of the narrative of Hamilton CJ's judgment. Later in the judgment, the Chief Justice referred (at 126) to an individual's "right to privacy, including self-determination", as though he regarded the latter as a species of the former, generic, right.

- 65 *Id.*, at 132.
- 66 *Id.*, at 156.
- 67 *Id.*, at 164.
- 68 *Id.*, at 167. See also *id.*, at 169.
- 69 [1974] IR 284, at 326. See also Budd J :
"when the Preamble ... speaks of seeking to promote the common good by the observance of prudence, justice and charity so that the dignity and freedom of the individual may be assured, it must surely inform those charged with its construction as to the mode of application of its Articles.
- 70 [1950] IR 235, at 247-248.
- 71 [1950] 67, at 80-81.
- 72 [1976] IR 325.
- 73 [1974] IR 284.
- 74 *Id.*
- 75 [1980] IR 32.
- 76 [1965] IR 294.
- 77 [1981] IR 75.
- 78 *Id.*
- 79 [1984] IR 36.
- 80 *Id.*
- 81 [1987] IR 587.
- 82 [1992] 1 IR 1.
- 83 High Ct, 25 February 1997.
- 84 497 US 261 (1990).
- 85 *In re Quinlan*, 355 A. 2d 647 (1976).
- 86 [1996] 2 IR , at 163.
- 87 *Id.*, at 167.
- 88 *Id.*, at 134.
- 89 [1996] 2 IR, at 161-162.
- 90 *Id.*, at 156 (*per* Denham J).
- 91 [1965] IR, at 349. See also *id.*, at 348.
- 92 *Id.*, at 348-349.
- 93 High Ct, 27 October 2000. See further Martin, 'Parental Rights to Withhold Consent to Medical Treatment for their Child: A Conflict of Rights', 19 IR L Times 114 (2001).

Presentations by Professor William Binchy

Fluoridation: Ethical Issues

Introduction

Fluoridation in the public water system presents complex and fascinating issues of moral and political philosophy⁹⁵ against a background of a process of radical shifts in the values that command support in legislative and judicial centres of power in Ireland⁹⁶ and internationally. The present analysis seeks to identify the issues and to give them some structure. It does not argue in favour of any particular ethical position. Nor does it seek to address the empirical issues regarding fluoridation which are before the Forum. It attempts to discuss the subject without prejudice to whether fluoridation is completely beneficial or has damaging side effects.

Changing values in society

It may be useful, as an introduction to the subject, to refer briefly to the process of changing values. If we take the position at the beginning of the twentieth century, there was broad social agreement on the limits of personal autonomy and substantial (though less clear) agreement on the role of the State in directing individual behaviour towards certain ends. So far as the limits of personal autonomy were concerned, there was general acceptance that individuals did not have the entitlement to kill themselves⁹⁷ or to injure themselves physically or morally. There was near consensus on what moral injury meant: lives of idleness, drunkenness or sexual indulgence were characterised as immoral in late Victorian times without significant social debate.

Today the predominant values internationally relating to personal autonomy have changed radically. Suicide is no longer a criminal offence⁹⁸. Voluntary euthanasia has gained significant support. Forced feeding is no longer practised and is now characterised as unlawful⁹⁹. Legal restraints on self-induced physical injury have been in some respects reduced, though in others (such as the requirement to use seat-belts¹⁰⁰) extended. Legal restraints on self-induced moral injury have also been reduced¹⁰¹ and there is a continuing debate about possible further reductions.

There are of course, several reasons for these changes. The cohesive influence of religion has weakened. In the philosophical world there has from the early years of the twentieth century been a substantial assault on the meaning or sense of normative, non-verifiable propositions, with logical positivists stigmatising such propositions as mere expressions of the speaker's emotive response to facts rather than as containing any truth content. Marxist and later post-modernist insights into the relationship between the forces of power in society and the predominant values have encouraged further scepticism about the objectivity of values. In a world where there is no longer broad social agreement as to the meaning and purpose of life or the objectivity of values, it is scarcely surprising that there should have been a movement from the social to the individual and that moral systems have become rooted in individualism, with emphasis on autonomy and disconnectedness.

Changing perceptions of the role of the State

Social attitudes to the role of the State in directing the individual towards certain ends involve somewhat more subtle changes over the past century. Naturally, the move to individualism has had the effect of weakening the role of the State in important areas. It is no longer considered appropriate for the State to have laws prohibiting suicide, aspects of drug use or consensual sexual activity. But this does not mean that the overall role of the State has shrunk over that period. On the contrary, the State has assumed very wide-ranging new functions, designed to achieve several goals: enhancing social welfare, encouraging equality, protecting citizens from injury, improving their health, protecting potentially vulnerable groups such as employees and, within families, children - indeed, seeking generally to improve the quality of life for all. To late Victorians, the proper role of the State was far more modest: to provide an infrastructure of physical protection from external attack or internal subversion, to protect property, to provide basic education and environmental protection but otherwise leave the citizens to work out their relationships with minimal State control.

It would be utterly simplistic and untrue to suggest that the movement over the past century has involved an uncomplicated shift towards socialism. Manifestly, there is an ongoing debate between capitalist free market principles and those of social democracy. Communism, and strong socialism, have been out of favour in recent years. Nevertheless, even in capitalist, right-of-centre regimes, the level of State participation and intervention in the lives and choices of individuals is much higher than it was a century ago and public health is regarded as an important aspect of the State's responsibilities.

Judicial changes

At this point it may be useful to note the changes that have taken place in the legal system over the past century so far as they affect analysis of the ethical issues raised by fluoridation. Two phenomena have had a huge influence: the growth of judicial review of legislative and executive action and the judicial recognition of previously unarticulated personal rights reflecting autonomy-centered values, notably those of privacy, dignity and bodily integrity. The first of these is reflected in the growth of constitutionalism¹⁰² and the adoption of international human rights instruments, such as the European Convention on Human Rights¹⁰³ and the International Convention on Civil and Political Rights.¹⁰⁴ The second is largely a cultural phenomenon in which the values that have gained currency in certain elites have affected the professional analysis of one such elite, the judiciary.

Fluoridation: A framework for ethical analysis

We now come to the central questions relating to ethical aspects of fluoridation.

Let us attempt to set a framework for our analysis. Fluoridation in the public water supplies involves, in practice, the introduction of a particular substance, under sanction of law, into the body of an autonomous adult, without necessarily that adult's willing acceptance of that process. What general ethical principles at the start of the twenty-first century concerning

the relationship between the State, the individual and legal sanctions can throw light on the specific phenomenon of fluoridation in public water supplies?

(i) Sanctions on conduct damaging to others

Let us begin with the case where the autonomous adult *engages in conduct damaging to others*. This contrasts with the case of fluoridation, where the adult is essentially a passive and possibly unwilling recipient of the fluoridation.

It is universally accepted that the State is entitled to prosecute and punish a person for having engaged in conduct that caused injury or damage to another or to society. This is achieved through the criminal law system. That system is subject to important limitations on the exercise of State power. In Ireland, these include the right to trial by jury¹⁰⁵, the presumption of innocence, the right to silence¹⁰⁶, the requirement that offences be defined with clarity¹⁰⁷, that investigation of suspected offences be conducted with due process¹⁰⁸ and that sentencing of offenders be proportionate¹⁰⁹. So far as punishment is concerned, the supreme invasion of bodily integrity - capital punishment - has been abolished by legislation¹¹⁰ but most commentators have accepted that capital punishment is not unconstitutional. One could not rule out, however, the growth of an analysis, fuelled by developing values relating to human dignity, to the effect that the death penalty is no longer consistent with the Constitution.

Undoubtedly, imprisonment involves a massive intrusion on an offender's liberty, right of association and in some cases, health. These intrusions on bodily integrity, autonomy and health find their justification in the value-judgment that an offender, by committing a criminal offence, is deserving of such punishment, which must be proportionate to the offence. It should be reiterated that internationally the value-judgments in this context have been changing radically over the past generation. There is very widespread condemnation of capital punishment, which has been reflected in the international jurisprudence of constitutional law¹¹¹ and international human rights instruments¹¹². Moreover, there is increasing revulsion with corporal punishment. Thus, the idea that the State is entitled to invade the bodily integrity of those who have been convicted of crime has become controversial, the old certainties gradually being replaced by a new belief, hardening into a certainty, that the State has no such entitlement.

(ii) Sanctions on conduct damaging to oneself

Let us now consider the position in relation to the prosecution and punishment of offences involving conduct by an autonomous adult that involved damage *only to himself or herself*. As we have seen, there has been a shift in values away from seeking to criminalise such conduct. The philosophical rationale for such a shift goes back to John Stuart Mill¹¹³ but the societal changes did not occur until the latter part of the twentieth century.

Damage in this context can embrace physical bodily damage (such as the damage that consumption of drugs, including alcohol, can cause) or even death (in the case of suicide). It can also embrace moral damage, such as may arise in the context of particular sexual

activities which, on certain moral premises, may be regarded as damaging to the moral integrity of the actor. The lines between physical damage to self, damage to others and moral damage to self can be difficult to draw. If, for example, a parent drinks a bottle of whiskey every day, could not the damage be considered to arise under all three of these categories? Moreover, the failure to use a seatbelt risks, not only damage to the negligent non-user, but also financial and psychological harm to the members of his or her family and financial damage to the wider community.

The strong trend of international values is towards opposing criminal sanctions for self-directed morally harmful conduct. This can be attributed to many factors, some of which have been mentioned: the decline in religion, the increasing philosophical debate about the objectivity of ethical judgments regarding human conduct, the concomitant growth in ethical systems centred on individual judgment and, in the case of sexual activities, changes in the technology relating to procreation¹¹⁴.

(iii) Prevention of conduct damaging to others

Let us now consider the next step in the analysis, taking us somewhat closer to the issue of fluoridation. This concerns the legal steps that the State may take by way of *intervention to prevent a person from acting in a way that will (or is likely to) cause harm to others*. What is striking about the values that underlie the present position is the principle of restraint that is the common denominator. Thus we find that it is not an offence to intend to commit a crime, even where the intent can be proved beyond any reasonable doubt. Nor is it an offence to prepare to commit an intended offence unless one has crossed the threshold of actually *attempting* to commit the offence. That threshold is placed very close to the actual consummation of the offence.

There are some extensions to this narrow proximity. Conspiracy to commit an offence does not require proof of actual attempt, though it is fair to say that the predominant contemporary values are hostile to resort by the State to this category of offence. Possession of certain types of property, such as guns, drugs or counterfeit machinery, may constitute an offence where the circumstances indicate that the possession is accompanied by a specific unlawful intent. Moreover, dangerous or careless driving or driving above the prescribed limit for alcohol is an offence by reason of the danger this involves of causing harm to others. Recently, the Oireachtas has created a specific generic offence of endangerment¹¹⁵. It would be fair to say that the criminal law does not intervene into people's lives unless they choose actually to commit offences, attempt or conspire to do so or engage in conduct that itself is redolent of such an attempt or the likelihood of an unintended, recklessly induced harmful outcome.

In an area related to the possession of suspected offences - bail - the restraint of the law is worthy of particular attention. The Supreme Court has held¹¹⁶, and reiterated¹¹⁷ its holding, that the likelihood that a person accused of an offence will engage in criminal conduct is *not* a reason for denying that person the entitlement to bail. To deny bail on the suspicion - even the well grounded suspicion - of future wrongdoing offends against the constitutional guarantee of liberty. This liberal stance of the Supreme Court - unrivalled anywhere else in

the world - was compromised by an amendment to the Constitution in 1997¹¹⁸, which received the substantial support of those voting.

When one steps outside the criminal context, one finds that ethical values inform the imposition of coercive controls of individuals in certain circumstances dictated by concern for the possibility that those individuals, if not subject to control, are likely to harm other persons. These cases include situations where a person with a psychiatric illness or behavioral disorder constitutes a threat to others¹¹⁹ or a person suffers from an infectious disease¹²⁰.

Again we can note the strong arguments against undue restraint by the State. This is particularly apparent in the context of people with AIDS or HIV, where there have been eloquent voices against restrictive measures such as quarantine or even less restrictive measures such as reporting obligations¹²¹.

(iv) Prevention of conduct damaging to oneself

Let us now consider the position in relation to strategies adopted by the State *to prevent harm to self*, as opposed to others. As we have seen, the general trust of value judgments in this context is towards abandoning such strategies. So far as the risk of suicide is concerned, the predominant value judgment is against legally-supported intervention by agents of the State to prevent a person who is not mentally ill from killing himself or herself. Forced feeding is no longer generally practised and is regarded today as being unlawful. The constitutionally-protected values of privacy¹²², autonomy¹²³, dignity¹²⁴ and bodily integrity¹²⁵ weigh heavily against State intervention in this area. There are, however, some exceptions to this approach. Laws prohibiting drug possession or requiring the use of seatbelts force individuals to act for their own good, against their inclination.

(v) Affirmative obligations to act for the benefit of others

The next question that must be addressed is the *obligation of one person to take positive steps to assist another or, more generally, to assist society*. Traditionally the law in common law jurisdictions¹²⁶ has been slow to recognise enforceable obligations of this character. Thus a person is not generally under a legal obligation to rescue another whose life is in peril, even where the rescue entails no danger (as, for example, where a toddler is drowning in shallow water). An enforceable legal obligation of an affirmative nature does arise in the context of a limited number of relationships, such as between parents and children and employer and employee. Even in these cases, the scope of the duty falls well short of unmitigated altruism. Moreover, the duty, when recognised, is essentially one arising from a situation of immediate danger or necessity where the beneficiary of the duty is in peril of injury or death. The duty does not extend to conferring a positive benefit outside these urgent circumstances. It is hard to conceive of cases where individuals are required to act for the positive benefit of society (as opposed to be prevented from acting to its detriment). Army conscription (where it still exists) is perhaps one such example. The obligation to pay taxes may be considered as another, albeit somewhat indirect, instance.

(vi) Affirmative obligations to act for the benefit of oneself

The next logical step is to ask whether an individual can be forced by the State *to act in a way that confers a positive benefit on himself or herself*, as opposed to being prevented from acting in a way that is damaging to himself or herself. The answer appears to be no. There seems general acceptance of the notion that the State's goal should go no further than (at most) discouraging harmful conduct, to self or others and resist the temptation to require individuals to act in a way that is good for them. Perhaps laws requiring compulsory attendance at religious services were examples of such an attempt but they have few counterparts today, even in relation to temporal benefits.

(vii) Controls on State action impacting on citizens

Having considered up to now the predominant value judgments relating to State attempts to control the *conduct of its citizens*, it is now necessary to analyse the moral restraints on the *conduct of the State itself* in seeking to achieve desirable goals. As may readily be appreciated, this issue is at the heart of the fluoridation process.

Of course the State has no physical reality: it is an abstraction which finds its existence in the realm of political philosophy. Nonetheless, the State does operate in the empirical order through its agents: soldiers, members of the Gardaí, public health inspectors, prison governors and so on. These people have very real powers, of a physical nature, to act in a way that will impact on citizens. So, for example, a prisoner may be incarcerated for many years, even for life; a person suspected of having committed an offence may be arrested and taken to a Garda station; a whole range of people may find their premises (including their homes) entered by an array of officially-authorized persons¹²⁷ and items of their property seized¹²⁸. The State can and does use its muscle to accomplish goals that are considered desirable.

What is striking about these intrusions, however, is the level of restrictions that surround them. They generally relate to situations where a criminal offence is reasonably suspected of having been committed or has actually been committed. The extent of the particular intrusion is narrowly and proportionately defined. Far from evidencing a general, unproblematic moral principle that the State may intrude physically into the lives of its citizens, these specific instances are more consistent with the directly opposite principle that the State has no such general entitlement to intrude and that its entitlement to do so in particular instances is severely restricted in its scope.

What is also striking is the differentiation made in respect for the different *types of intervention*. Thus, while it is (increasingly) accepted that a range of persons should have powers of entry onto premises in support of law enforcement goals, it is also recognised that there is a crucial difference between entering a business premises or an open field, for example, and entering a person's *home*. In order to justify an intrusion into this quintessentially private zone, the law sets a higher standard and generally requires prior judicial authorisation.

So also in relation to physical contacts with a person's body. Here, there is universal acceptance of the moral principle that such contacts by an agent of the State should be justified in only serious circumstances where something of great importance is at stake. In the context of the detection of offences, the law has proceeded very cautiously. It was only in 1984 that significant entitlements to engage in intrusions into the body¹²⁹ of a suspected person were conceded and even here, there are limits to what is permissible. In civil proceedings, the restraints are understandably even greater. It is not possible to force an autonomous adult to subject himself or herself to undergo a blood test where parenthood is in issue: all that can be done is permit the court to draw such inferences from a refusal to undergo it as appear proper¹³⁰.

Vaccinations present particular difficulty. There is a major debate as to whether compulsory vaccination is morally permissible. The argument in favour is, of course, that without compulsion the benefits to the community, and thus to the individuals who make up that community, will be lost since the efficacy of vaccinations is contingent on a high take-up rate. The argument against is that even a highly desirable social goal may not be achieved through coercive intrusion of an individual's body. At the heart of this argument is the notion that a person's body is a zone of particular privacy and that a coercive intrusion, even for a good goal, violates the autonomy, privacy and dignity of the individual in a unique way.

Between these two competing positions, a middle ground finds much contemporary support. According to this approach, coercive intrusions upon a citizen's body by agents, or through the agency, of the State may be justified for serious reasons where the intrusion is proportionate. Of course, this immediately raises debate as to how serious these reasons would have to be and how proportionality can be achieved.

If we move still closer to the fluoridation issue and ask whether moral objection could be taken to the inclusion of chlorine in the water supply, the answer would clearly appear to be no. Applying the twofold criteria, of serious reason and proportionality, the inclusion of chlorine can be justified in that it is an essential ingredient for making the water safe for consumption. While it may conceivably have a detrimental effect for some small number of citizens, the overall benefits, coupled with the necessity for its inclusion, maybe considered to render it a proportionate intrusion on citizens' rights of privacy, autonomy, dignity and bodily integrity.

Fluoridation: balancing public health values with autonomy-centred values

After this long journey let us now consider the fluoridation process itself. It need hardly be said that, if fluoridation causes serious injury, such as cancer, on a significant scale, its compulsory inclusion in the public water supply could not be morally justified. The benefits that it seeks to achieve would not be a sufficient counterweight. For the purposes of the present analysis, it will be assumed that fluoridation does not cause such serious injury. The analysis proceeds on the premise that fluoridation has some limited negative effects and that it succeeds in its goal of benefitting the community by contributing to the reduction

in tooth decay. While proceeding on this premise, it ought to be acknowledged clearly that the detail of the scientific debate is of importance to the moral assessment of the position. This is because the issue of proportionality, which is at the heart of the question, is clearly dependent on the precise benefits that must be weighed against the precise debits which the process involves.

The moral values weighing in favour of fluoridation in the public water supplies are obvious. The public health goal of reducing tooth decay in the community is fostered. The process involves effective access to particular groups of society who are otherwise difficult to reach.

The countervailing moral values are equally easy to identify. The process involves an introduction into the bodies of citizens of material to the introduction of which they do not necessarily provide their consent. The benefit which it confers is one that they arguably should be free to decline and is one that they can in any event confer voluntarily on themselves by other means. The important values of privacy, autonomy, dignity and bodily integrity are compromised for what some consider to be a relatively trivial benefit. If these important values are to be overridden, it may be argued that the reason should be a serious one, and the benefit should be incapable of being conferred in any other less intrusive way.

To these objections it can perhaps be replied that we should retain a sense of reality. The "incursion" that the intake of fluoride involves is overwhelmingly beneficial¹³¹. If the State laboured to ensure that citizens breathe clean air rather than smog, it would be eccentric for a citizen to complain about the violation of bodily integrity that this involves and the denial of his or her right of access to a smoggy atmosphere. The fact that water has been subjected to the inclusion of an additional substance is not crucial, any more than the addition of chlorine to water is problematical. The important question is whether the water, thus transformed, is beneficial or harmful to the user.

It may be useful to reflect on the implications in the present context of differing models of public health.¹³² One model concentrates on the pursuit of microbes: it regards the primary function of public health as being to prevent the spread of communicable diseases. On this model, issues will arise in regard to such matters as compulsory isolation or quarantine, notification requirements and compulsory vaccinations. A second model regards public health as being concerned with controlling human behavior, such as smoking and diet, by incentives and sanctions. It has been observed that:

"behavioral theory invites what can be seen as paternalistic interference with personal choices. When government penalises high risk behavior, such as failure to wear a seatbelt or motorcycle helmet, or patronage of a bathhouse or sex cinema, it determines the behaviors in which citizens may or may not engage. This classically liberal objection most clearly applies to overt regulation of behavior - motorcycle helmet laws, for example - but also commonly extends even to governmental advice, on the ground that such a collective expression of proper behavior is inherently coercive."¹³³

A third model of public health, which has been characterised as the ecological model, regards health as essentially limited to social conditions. Thus the public health goals will

be towards improvement in living conditions and social access to the supports for healthy living.

Clearly each of these three models is to some extent a caricature but nonetheless they do capture an important element in the discussion about values relating to fluoridation. None of them can, in their own expression, resolve the question of the extent to which compulsion may be permitted to override principles of autonomy and bodily integrity. Of the three, the first seems weakest in asserting a claim that State interests should take priority, since fluoridation is not concerned with controlling the spread of "contamination" from one person to another. The second model, based on controlling behaviour, is clearly premised on the acceptance of the legitimacy of the State interference with autonomy. The third model does not profess to confront the autonomy issue directly but its emphasis on the social context of health and the legitimacy of State policies addressing and transforming social reality is unsympathetic to a world view in which individualistic norms are predominant.

Concluding observations

The ultimate resolution of the ethical debate in relation to fluoridation will depend on the empirical facts. If fluoridation is harmful, then clearly its compulsory inclusion in the water supply cannot be justified. If, however, it is not harmful, there still remain important ethical issues for resolution. This paper has concentrated on them in the hope of elucidating discussion.

- 95 For general discussion see Mann, Gruskin, Grodin & Annan, *Health and Human Rights: A Reader* (1999), Häyry, *Individual Liberty and Medical Control* (1998) (especially Chapter 5), Dworkin, 'Paternalism', 56 *Monist* 64 (1972), reprinted in Gorovitz *et al* eds, *Moral Problems in Medicine* (1976), p. 185, Childress, 'Rights to Health Care in a Democratic Society', in Humber & Almeder eds., *Biomedical Ethics Reviews: 1984*, p.47, Childress, *Who Should Decide? Paternalism in Health Care* (1982), Chapter 5, Beauchamp, 'Public Health as Social Justice', 13 *Inquiry* No. 1 p. 3 (March 1976), reprinted in Mappes & Zembaty, *Biomedical Ethics* (1981), p. 551, Horner, 'Preventive Medicine and Integration of Health Services', Chapter 12 of Scorer & Wing eds., *Decision Making in Medicine: The Practice of Its Ethics* (1979), Remington Graham & Morin, 'Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies', 14 *J of Land Use & Environmental L* 195 (1999), Balog, 'Comment: Fluoridation of Public Water Systems: Valid Exercise of State Police Power or Constitutional Violation?', 14 *Pace Environmental L Rev* 645 (1997), Shapiro, 'Courts, Legislatures and Paternalism', 74 *Virginia L Rev* 519 (1988).
- 96 See Hamilton, 'Matters of Life and Death', 65 *Fordham L Regv* 543 (1996), Whyte, 'Religion and the Irish Constitution', 30 *J Marshall L Rev* 725 (1997).
- 97 Thus suicide was an offence prior to its abolition in 1993.
- 98 Criminal Law (Suicide) Act 1993.

- 99 *Secretary of State for the Home Department v Robb* [1995] Fam 127, *Burke v Government of Prince Edward Island* 1991 ACW 5J LEXIS 4598 (PEI Sup. Ct., 26 July 1991), *Department of Immigration v Gek Bony Mok*, 1992 NSW LEXIS 6493 (NSW Sup. Ct., 30 September 1992). See further Byrne & Binchy, *Annual Review of Irish Law* 1998, pp. 601-603.
- 100 See McMahon & Binchy, *Irish Law of Torts* (3rd ed., 2000), paras. 20.34 - 20.45. Controls on smoking may be regarded as being primarily directed to the protection of others rather than of the smoker himself or herself. Such latter protection is limited to prohibitions on sales to young persons and on advertising and the requirement of a health warning on cigarette packets.
- 101 Thus, in a number of jurisdictions possession of certain drugs such as cannabis is either not an offence or treated in practice as not worthy of prosecution. So far as consensual sexual activity is concerned, the criminal restraints have been largely removed and the age of consent reduced. (The perception of such activity as involving "moral injury" has also faded).
- 102 As to the Irish position, see J Casey, *Constitutional Law in Ireland* (3rd ed., 2000), Kelly, *The Irish Constitution* (3rd ed., by G Hogan & G Whyte, 1994).
- 103 See Harris *et al*, *Law of the European Convention on Human Rights* (1995).
- 104 See Gaja, 'New Instruments and Institutions for Enhancing the Protection of Human Rights in Europe?', Chapter 24 of Alston ed., *The EU and Human Rights* (1999).
- 105 Article 38.5 of the Constitution. See Kelly, *The Irish Constitution* (3rd ed., by G Hogan & G Whyte, 1994).
- 106 See Hogan, 'Constitutional Law - The Right to Silence After *National Irish Banks* and *Finnerty*' [1999] Dublin U L J 176.
- 107 *Kings v Attorney General* [1981] IR 223.
- 108 See Kelly, *The Irish Constitution* (3rd ed., by G Hogan & G Whyte, 1994), pp. 572ff.
- 109 See the Law Reform Commissions, *Report on Sentencing* (LRC 53 - 1996).
- 110 Criminal Justice Act 1990, section 1.
- 111 See Bogie, 'Note: Life or Death? The Death Penalty in the United States and the New Republic of South Africa', 3 *Tulsa J of Comp & Int'l L* 229 (1996), Bouckaert, 'Note: Shutting Down the Death Factory: The Abolition of Capital Punishment in South Africa', 32 *Stanford J of Int'l L* 287 (1996), Falk & Cary, 'Death-Defying Feats: State Constitutional Challenges to New York's Death Penalty', 4 *J of L & Policy* 161 (1995)
- 112 See Schreiber, 'Note: States that Kill: Discretion and the Death Penalty - A Worldwide Perspective', 29 *Cornell Int'l J* 263 (1996), Wyman, 'Comment: Vengeance Is Whose? The Death Penalty and Cultural Relativism in International Law', 6 *J of Transnational L & Policy* 543 (1997), de Ruiz-Bravo, 'Suspicious Capital Punishment: International Human Rights and the Death Penalty', 3 *San Diego Justice J* 379 (1995).
- 113 J. S. Mill, *On Liberty* (1859), reprinted in R Wollheim ed., *Three Essays* (1975). See Kelly, *A Short History of Western Legal Theory* (1992) pp. 339-340, 443-447, Häyry, *Individual Liberty and Medical Control* (1998), pp. 1-15.
- 114 See Madden, '*In Vitro* Fertilization: The Case for State Regulation', 13 *Ir L T (ns)* 298 (1995), Madden, 'The Quest for Legal Parenthood in Assisted Human Reproduction' [1999] Dublin U L J 1.
- 115 Non-Fatal Offences Against the Person Act 1997, section 13.
- 116 *People v O'Callaghan* [1966] IR 501.

- 117 *Ryan v D.P.P.* [1989] ILRM 33. See Byrne & Binchy, *Annual Review of Irish Law* 1988, pp. 144-147.
- 118 The Sixteenth Amendment of the Constitution. See Byrne & Binchy, *Annual Review of Irish Law* 1997, pp. 277-283.
- 119 See *Tarasoff v Regents of University of California*, 529 P 2d 553, 118 Cal Rptr 129 (1974) and 551 P 2d 334, 131 Cal Rptr 14 (1976), critically analysed by Stone, 'The *Tarasoff* Decisions: Suing Psychoterapists to Safeguard Society', 90 Harv L Rev 358 (1976); cf. *Throne v Western Australia* [1964] WAR 147, *C v North Western Health Board* [1997] Ir L Log W 133. See further *Thapar v Zezulka* 994 S W 2d 635 (Texas, 1999), *Palmer v Tees Health Authority* [1999] Lloyds Rep. Med. 351, Cantu & Jones Hopson, 'Bitter Medicine: A Critical Look at the Mental Health Provider's Duty to Warn in Texas' 31 St. Mary's L J 359 (2000).
- 120 Cf. the Health Care Act 1947 and the Infectious Disease Regulations; the Public Health (Control of Disease) Act 1984.
- 121 See generally Casey & Craven, *Psychiatry and the Law* (1999), p. 109. O'Neill, 'Matters of Discretion - The Parameters of Doctor/Patient Confidentiality' 1 *Medico-Legal J of Ir* 94 (1995), the Medical Council of Ireland, *Guide to Ethical Conduct and Behaviour*, paras. 18.12-18.14, Carmody, 'Mandatory HIV Partner Notification: Efficacy, Legality and Notions of Traditional Public Health', 4 *Texas Forum of Civil Liberties & Civil Rts* 107 (1999), Stenger, 'Comment: Taking *Tarasoff* Where No One Has Gone Before: Looking at Duty to Warn under the AIDS Crisis', 15 *St Louis U Pub L Rev* 471 (1996).
- 122 *McGee v Attorney General* [1974] IR 284, *Norris v Attorney General* [1984] IR 36, *Kennedy and Arnold v Ireland* [1988] ILRM 472, *Re a Ward of Court* [1995] 2 ILRM 401. See McMahon & Binchy, *Irish Law of Torts* (3rd ed., 2000), paras. 37.60 - 37.98, Wintemute, *Sexual Orientation and Human Rights: The United States Constitution, The European Convention and the Canadian Charter* (1995), Thornton, 'The New International Jurisprudence on the Right to Privacy. A Head-On Collision with *Bowers v Hardwick*', 58 *Albany L Rev* 725 (1995), Whyte, 'The Right to Die under the Irish Constitution', 3 *Eur Public L* 235 (1997), Thompson, 'International Protection of Women's Rights: An Analysis of *Open Door Counselling Ltd. and Dublin Well Woman Centre v Ireland*', 12 *Boston U International L J* 371 (1994), O'Carroll, 'The Right to Die: A Critique of the Supreme Court Judgment in "the *Ward Case*"', 84 *Studies* 375 (1995), Feenan, 'Death, Dying and the Law', 14 *Ir L Times (ns)* 90 (1996), Tomkin & McAuley, '*Re a Ward of Court*: Legal Analysis', 2 *Medico-Legal J of Ir* 45 (1995).
- 123 *In re a Ward of Court* [1995] 2 ILRM 401; cf. *Walsh v Family Planning Services* [1992] 1 IR 496, *Geoghegan v Harris*, High Ct., Kearns J, 21 June 2000, Healy, *Medical Negligence: Common Law Perspectives* (1999), Chapter 5, Tomkin & Hanafin, *Irish Medical Law* (1995), Chapter 3, Lamb, *Therapy Abatement, Autonomy and Futility* (1995), Chapter 8.
- 124 *In re a Ward of Court* [1995] 2 ILRM 401; Feldman, 'Human Dignity as a Legal Value' [1999] *Public L* 682, [2000] *Public L* 61.
- 125 *Ryan v Attorney General* [1965] IR 294, *In re a Ward of Court* [1995] 2 ILRM 401.
- 126 See Bohlen, 'The Moral Duty to Aid Others as a Base of Tort Liability', 56 *U Pa L Rev* 217, 316 (1908), Linden, 'Rescuers and Good Samaritans', 34 *Modern L Rev* 241 (1971), Brady, 'Note: The Duty to Rescue in Tort Law: Implications of Research on Altruism' 55 *Indiana L J* 551 (1980), Ames, 'Law and Morals' 22 *Harvard L Rev* 97 (1908), Stewart,

- 'How Making the Failure to Assist Illegal Fails to Assist: An Observation on Expanding Criminal Omission Liability', 25 *Amer J of Crim* 385 (1998). One effect of the decision of the European Court of Human Rights in *Osman v United Kingdom* [1999] 1 FLR 193 may be to extend to common law jurisdictions the spirit of the civil law systems in this context: see McBride, 'Protecting Life: A Positive Obligation to Help' [1999] *Eur L Rev*, 24 Supp HRS 43-54; cf. von Bar, *The Common Law of Torts* (2000), vol. 2, pp. 208-232.
- 127 Dozens of statutory examples are cited by McMahon & Binchy, *Irish Law of Torts* (3rd ed., 2000), paras. 23.06-23.07. See, e.g., the Equal Status Act 2000, section 33, the Education (Welfare) Act 2000, section 30, the Copyright and Related Rights Act 2000, sections 133(5) and 257(5) and the National Minimum Wage Act 2000, section 33.
- 128 The most important generic provision is section 9(1) of the Criminal Law Act 1976, but there are dozens of other specific instances: see McMahon & Binchy, *Irish Law of Torts* (3rd ed., 2000), paras. 28.16-28.18. Recent statutory examples include the Illegal Immigrants (Trafficking) Act 2000, section 3 and the Electronic Commerce Act 2000, sections 27(2) and 27(5).
- 129 Criminal Justice Act 1984.
- 130 See *W. v W.* (No. 4), [1974] P 67; *H v H*, [1966] 3 All ER 560, the Status of Children Act 1987, section 39. As to the position regarding children, see section 39(3)(a), critically analysed by Byrne & Binchy, *Annual Review of Irish Law* 1987, pp. 188-189.
- 131 Assuming, of course, for the purposes of this argument that the criticisms of the process are misconceived.
- 132 See Gostin, Burris & Lazzarini, 'The Law and the Public's Health: A Study of Infectious Disease Law in the United States', 99 *Columbia L Rev* 59 (1999).
- 133 *Id.*, at 73.

Appendix 18

RISK ASSESSMENT OF THE FLUORIDE INTAKE OF IRISH INFANTS UNDER 4 MONTHS OF AGE AS A RESULT OF THE CONSUMPTION OF INFANT FORMULA RE-CONSTITUTED WITH FLUORIDATED WATER

The Scientific Committee of the Food Safety Authority of Ireland

Appendix 18 Risk assessment of the fluoride intake of Irish infants under 4 months of age as a result of the consumption of infant formula re-constituted with fluoridated water

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Risk assessment of the fluoride intake of Irish infants under 4 months of age as a result of the consumption of infant formula re-constituted with fluoridated water

The Scientific Committee of the Food Safety Authority of Ireland

Executive Summary

In May 2000 the Minister for Health and Children set up the Fluoridation Forum. It was mandated to explore all aspects of water fluoridation and its impact, both positive and negative, on the health of Irish citizens. The Food Safety Authority of Ireland (FSAI) is not directly responsible for the legislation on drinking water. However, the FSAI does have a statutory responsibility for the safety of water as a food ingredient. The FSAI was represented on the Fluoridation Forum and advised on aspects of food safety where required.

Following concerns raised at the Fluoridation Forum, the FSAI requested its Scientific Committee to conduct a risk assessment to determine if there is a risk of adverse effects in infants as a consequence of consumption of infant formula reconstituted with fluoridated tap water. The subset of the infant population likely to receive the highest fluoride intake from infant formula reconstituted with fluoridated tap water is represented by those infants below the age of 4 months for whom infant formula is the sole food source and consumption is high relative to body weight. A discussion of public health concerns related to reconstitution of infant formula with fluoridated water must however recognise, as a starting point, the previous position on infant feeding practices adopted by the FSAI (FSAI, 1999), which recognised the importance of breast-feeding. The intake of fluoride in breastfed infants is recognised to be very low.

Estimates were made of fluoride intake in infants aged 0-4 months using accepted norms for daily volume of infant formula consumption and body weight (b.w.) standards, together with measured values for the fluoride content of water for the years 1997/98 (Dublin) and 1999 (other regions) reported by the Environmental Protection Agency. The water fluoride data showed that although some water supplies reported considerable variation in fluoride measurements during the year, 95% of supplies achieved a yearly average measured water fluoride concentrations below 1.03mg/l. The statutory upper limit in Ireland is 1mg/l. The remaining 5% of supplies exceeded the statutory limit on a consistent basis, however the highest average fluoride concentration calculated in any of these non compliant supplies was 1.35mg/l.

The mean fluoride intake on any single day in infants aged 0 - 4 months ranged from 0.112 to 0.140mg/kg b.w./day depending on age group, with the 95th percentiles ranging between 0.196 and 0.259mg/kg b.w./day. However, the maximum average intake of fluoride from infant formula reconstituted with fluoridated tap water over the first four months of life was estimated to be in the range 0.105mg/kg b.w./day to 0.172mg/kg b.w./day, depending on

body weight. This intake was calculated for infants residing in areas served by the 95% of water supplies that achieved an average yearly water fluoride level of below 1.03 mg/l.

There is an extremely large epidemiological database on human response to a low intake of fluoride from tap water. It has been accepted by many expert groups at an international level which have reviewed these data that there is no substantive evidence that fluoride intakes in the range predicted for young infants by the exposure modelling in this risk assessment are associated with adverse health effects other than dental fluorosis. This view is endorsed by the Scientific Committee. The adverse effects observed in some animal studies are not considered relevant for the purposes of this risk assessment, since extensive epidemiological studies have not produced evidence that the findings in animals can be extrapolated to human populations drinking fluoridated water over many years.

It is recognised that fluoride intakes at levels obtained from fluoridated tap water may contribute to dental fluorosis, a dose response effect caused by fluoride ingestion during the pre-eruptive maturation of teeth. In its mild form, dental fluorosis has no effect on tooth function. Mild dental fluorosis is characterised by opaque striations on the teeth that can merge to form small opaque patches. Patches most often occur on the cusps of the posterior teeth or on the incisor edge of the anterior teeth. The changes of mild dental fluorosis are not readily apparent to the affected individual or casual observer and are often detected only by specialist examination. However, teeth that are affected by moderate to severe dental fluorosis are characterised by changes such as brown staining and surface irregularities which are readily apparent and aesthetically objectionable. Hence, in the context of this report, the unwanted effect considered to be of concern in relation to intake of fluoride from fluoridated water is moderate dental fluorosis.

There is a lack of agreement among expert groups on the tolerable upper intake level of fluoride in young infants. On balance, the Scientific Committee has accepted the widely held (although not universally accepted) view that the period over which the permanent teeth are most susceptible to dental fluorosis is not in infancy but from 15 to 24 months of age for boys and 21 to 30 months for girls. During early infancy it is the primary teeth which are in the developmental stage and which are therefore most likely to be susceptible to dental fluorosis. Although there are no data on the prevalence of dental fluorosis in primary teeth in children in Ireland, studies from other countries show that there is very little risk of moderate fluorosis in primary teeth, particularly the anterior teeth, at the levels of fluoride intake estimated for infants consuming infant formula reconstituted in fluoridated tap water in Ireland.

The following conclusions can be drawn about the possible risks to young infants from the consumption of infant formula reconstituted with fluoridated tap water at current levels of fluoride addition in Ireland.

1. There is no significant evidence that any adverse effect other than dental fluorosis is relevant to the assessment of the risk of fluoride intake at levels within the range estimated for young infants in this risk assessment.

2. The risk of moderate dental fluorosis of the primary or permanent dentition is very low in exclusively formula-fed infants aged 0 to 4 months residing in areas served by the 95% of supplies in which the level of fluoride in water does not exceed the statutory limit. For the remaining infants residing in areas served by the 5% of supplies that consistently exceed the statutory limit, the risk is also considered to be very low, but the safety margin is reduced.

In the absence of data on the prevalence of dental fluorosis in primary teeth in children in Ireland, the Committee recommends the following precautionary measures:

1. All tap water supplies in Ireland should be brought into compliance with the statutory fluoride limits for drinking water.
2. The statutory limit for fluoride in tap water should be examined with the aim of reducing it to the lowest level necessary to achieve the desired level of protection against dental caries.
3. The intake of fluoride in infants and the prevalence of dental fluorosis in infants and children should be monitored on an ongoing basis.

The Committee also reiterates the advice of the FSAI (FSAI, 1999) that:

'all babies should be breastfed, except in very rare cases when breastfeeding is medically contraindicated; exclusive breastfeeding should be practised during the first four to six months of life'

Background

The Food Safety Authority of Ireland (FSAI) is charged with the protection of consumer health from hazards in foodstuffs. The FSAI is not directly responsible for the legislation on drinking water. However, water is a primary component of many foodstuffs and the FSAI does have a statutory responsibility for the safety of water as a food ingredient.

The Fluoridation Forum set up by the Minister for Health and Children was mandated to explore all aspects of water fluoridation and its impact, both positive and negative, on the health of Irish citizens. The FSAI is represented on the Fluoridation Forum and advises on aspects of food safety where required.

Following concerns raised at the Fluoridation Forum, the FSAI requested its Scientific Committee to conduct a risk assessment to determine if there is a risk of adverse effects in infants as a consequence of consumption of infant formula reconstituted with fluoridated tap water.

Scope of the risk assessment

The human population varies considerably in its response to individual substances. Toxicological effects depend on dose and the susceptibility of the individual to the toxic agent. Susceptibility is moderated by factors such as age and health status, whereas the level of exposure and the bodyweight moderate the individual dose. Young babies constitute a susceptible sub-population, considered as particularly vulnerable because they are at a critical stage in their development. Infants that are not breastfed consume high volumes of infant formula relative to their body weight. Thus the fluoride intake from infant formula reconstituted with fluoridated tap water is likely to be highest in formula-fed babies below the age of 4 months.

The toxicology of fluoride is a complex subject and this report is not intended to be a detailed review of the subject. Therefore, the report provides a condensed overview of relevant literature and published reports. It is accepted that there may be widely different opinions concerning the toxicology of fluoride, but these cannot be reflected comprehensively within the scope of this report.

In Ireland there are no data on the food consumption patterns of infants. This prevented the use of measured data on the consumption of infant formula and restricted the exposure assessment to exclusively formula-fed infants less than four months of age. As a solution to the absence of measured data, a modelling approach was used to predict the likely intakes of fluoride ingested by infants below four months of age as a result of the consumption of infant formula reconstituted with fluoridated tap water. These predictions are only a guide to the actual exposure of infants to fluoride. The exposure assessment was carried out using accepted probabilistic modelling methodology and was based on available data where identified. However, where data was not identified, expert opinion was sought to underpin any assumptions made. Where assumptions were made, they are clearly identified.

Aim of the report

To make an estimate of the intake of fluoride in formula-fed infants based on the available published data, expert opinion and informed assumptions, and to determine if there is a risk to infants due to their intake of fluoride from consumption of infant formula reconstituted with fluoridated tap water.

Risk Assessment

Risk assessment is a systematic process based on science. There are four steps in carrying out a risk assessment of hazards in foods. These are:

- Hazard identification
- Hazard characterisation
- Exposure assessment
- Risk characterisation

The structure of the report addresses each of these steps in sequence.

Hazard Identification for fluoride

Fluoride is the ionic form, F^- , of the chemical element fluorine. Fluoride binds ionically to a range of cations, e.g. sodium, potassium, calcium, to form inorganic fluorides, and may also form more complex fluorides with other anions and cations, e.g. sodium monofluorophosphate, used commonly in toothpaste and hydrofluorosilicic acid, used commonly in fluoridation of water supplies. There is no clear evidence that fluoride is an essential element, either in the human body or in toxicological studies in animals.

The toxicokinetics and toxicodynamics of absorbed inorganic fluoride are independent of the fluoride source (Thiessen, 1988). Inorganic fluoride is believed to be transported across biological membranes by passive diffusion, primarily in the non-ionised form (hydrogen fluoride, HF). Absorption from the gastrointestinal tract is rapid after oral administration, and is inversely related to the pH of the gastric contents. Bioavailability is influenced by the presence of fluoride-binding cations such as magnesium, aluminium and in particular calcium (Canadian Environmental Protection Agency (CEPA), 1993; Janssen, 1989; WHO, 1984). Dunipace *et al.* (1998a) have shown 92 - 94% bioavailability of administered fluoride in rats fed a diet containing 0.125% calcium, 76 - 78% bioavailability when the diet contained 0.25% calcium and 58 - 64% when it contained 0.5%. Absorption is essentially 100% in the fasted state. At physiological pH in blood, intercellular fluid, etc. non-protein or lipid bound fluoride exists primarily in the ionised form (F^-); only 0.01 % of the total free fluoride concentration exists as the non-ionised form. After uptake fluoride is transported in the blood, 75% of total blood fluoride concentration being found in the plasma, the remainder being associated with the red blood cells. About 50% of the fluoride in serum is bound to organic molecules, mainly in perfluoro-fatty acids (WHO, 1984). At normal fluoride intakes and uptake from the gastrointestinal tract, plasma fluoride levels are in the range 10 - 20 $\mu\text{g/L}$ or 0.5 - 1.0 μM (Ekstrand, 1978). Fluoride levels in plasma are directly related to the level of exposure (Morris and Smith, 1982; WHO, 1984; NTP (US National Toxicology Programme) 1990; Maurer *et al.*, 1990; Maurer *et al.*, 1993), and plasma half-lives of 2 to 9 hr have been reported in humans (WHO, 1984).

Absorbed fluoride is rapidly and uniformly distributed to soft tissues and to bones and teeth. It is also thought to cross the placenta and reach the foetus. Since soft tissue fluoride is in equilibrium with the plasma pool, similar half-lives to those reported for plasma may be assumed for soft tissue. There is no accumulation of fluoride in soft tissues, levels are under homeostatic control. However, sequestration and accumulation of fluoride occurs in bone and teeth, in which it is incorporated into the mineral structures by exchange with the hydroxyl and carbonate ions of hydroxyapatite.

About 50% of absorbed fluoride is deposited into bone structure where it is reported to have a mitogenic action, resulting in stimulation of osteoblast proliferation (Libanati *et al.*, 1996). However, in younger humans and in the elderly, bone fluoride uptake is higher than in middle age. As for plasma, fluoride levels in bone are directly related to the level of exposure. Fluoride in bone is released and eliminated from the body following cessation of exposure, with an estimated half-life in the range of 8 to 20 years (WHO, 1984). Fluoride continues to deposit into the calcified structures after the other constituents of bone have already reached a steady state. The major constituents of bone - calcium, phosphorus, magnesium, carbonate, citrate - reach their maximum levels early in life and remain essentially unchanged, even after administration of large amounts of the ion in question. Fluoride, on the other hand, shows a tenfold increase in bone following ingestion of drinking water with fluoride levels of < 1.0 up to 4 mg/l.

The major route for excretion of fluoride is via the urine. In animals and humans excretion into urine occurs via glomerular filtration, after which reabsorption as HF may occur in the renal tubules. This process is dependent on urinary pH. In acidic urine a relatively high proportion of excreted fluoride will be present as the non-ionised HF and will be reabsorbed, whereas in alkaline urine the excretion of fluoride will be enhanced. Minor routes of excretion are via faeces, saliva (partial reabsorption after ingestion) and perspiration. Excretion via breast milk appears to be an insignificant route of elimination (Thiessen, 1988).

The majority of toxicological data on fluoride in animals in the scientific literature have been generated using the relatively bioavailable sodium fluoride. There is a dearth of specific studies on other forms of fluoride such as hydrofluorosilicic acid. It is generally accepted, however, that the toxicity of inorganic fluorides is primarily related to the fluoride ion and is largely independent of the nature of the cation. Fluoride has been shown to be acutely toxic in studies in animals and cases of human poisonings have also been reported. The primary effect of chronic excess fluoride in both humans and animals is an adverse effect on bone and dental enamel, resulting in dental and skeletal fluorosis. A recent systematic review of the literature concluded that there was a strong association between water fluoride concentration and the proportion of the population with dental fluorosis (McDonagh *et al.*, 2000). The potential adverse effects of fluoride are described in more detail in the hazard characterisation section below and also in Appendix 1.

Hazard Characterisation

There is contradictory evidence, both in humans and animals, concerning possible adverse effects on health as a result of fluoride ingestion (Fluoridation Forum, 2000/1). Reported oral LD 50s¹ in animals generally lie in the range 50 - 60 mg/kg (for fluoride ion), with values as low as 25 mg/kg and as high as 100 mg/kg being reported. Repeat dose animal studies show that fluoride produces changes in bone and dental enamel, occurring at dose levels below 1 mg F⁻/kg/day and accompanied by body weight and organ weight changes. Electrolyte imbalances and blood biochemical changes have also been reported. The overall results of carcinogenicity and genotoxicity studies suggest that fluoride is not a carcinogenic substance in animals, although a low incidence of osteosarcomas was reported in male rats in one carcinogenicity study. Genotoxicity studies show some evidence of a genotoxic potential of fluoride *in vitro*, but only at cytotoxic concentrations with low cell survival. There is no evidence that fluoride is genotoxic in *in vivo* studies. Reproductive toxicity studies have shown no developmental toxicity following administration of fluoride in drinking water at dose levels up to 300 mg/l, other than some embryotoxicity. The NOAEL (No observable adverse effect level) in these studies was greater than 10 mg F⁻/kg b.w./d. There are no published studies on developmental effects relating to high postnatal fluoride intake. Although there are reports that fluoride can produce testicular toxicity in rats and thus potentially reduce male rat fertility, a recent multigeneration study carried out by the US FDA showed no effect on the testis or on fertility at dose levels up to 250 mg/kg b.w./d. The toxicological studies demonstrate that fluoride is toxic to animals, following acute exposure and also prolonged exposure to non-physiological levels.

The traditional toxicological approach to setting a safe threshold level for fluoride uses the results of animal studies to establish a 'no observed adverse effect level' (NOAEL). This level is further reduced by safety factors depending on the severity of the toxicological effects observed in animals and inter and intra species variation, to arrive at a threshold intake (e.g. tolerable daily intake, TDI, or tolerable upper limit, UL) for humans. However, in the case of fluoride, there is an extremely large epidemiological database on human response to a low intake of fluoride from tap water. It is therefore considered more appropriate to base the hazard characterisation step of this risk assessment on the available human data, rather than the animal data. For this reason, primary emphasis in this hazard characterisation has been given to the studies in humans, and the results of the animal studies have been provided as a brief summary in this section, as above. A more detailed description of these studies is provided in Appendix 1.

Health effects of fluoride in humans

Acute toxicity

Reports of human poisoning cases in the literature indicate that the lethal dose of sodium fluoride in humans is in the range of 5 - 10 g, death being preceded by nausea, vomiting

¹ The dose that has a lethal effect in 50% of a group of animals studied

and abdominal cramping. Based on the results in animal studies and the above human poisoning studies, acute toxic effects of fluoride can be predicted to occur in the range of 50-100mg/kg F⁻ b.w./day.

Toxicity following prolonged exposure to fluoride

The United States Institute of Medicine, in determining dietary reference intakes for fluoride, stated that the primary adverse effects associated with chronic excess fluoride intake were enamel (dental) fluorosis and skeletal fluorosis (US Institute of Medicine, 1999). Dental fluorosis is further addressed in the next section of this report.

In relation to skeletal fluorosis, an early (pre-clinical) symptom of exposure to high levels of fluoride in humans is an increase in bone mass. Sporadic pain and joint stiffness, chronic joint pain, osteosclerosis of cancellous bone and calcification of ligaments are seen in the first and second clinical stages. In stage 3, limitation of movement of joints, skeletal deformities, intense calcification of ligaments, muscle wasting and neurological deficits are found (CEPA, 1993; ATSDR (Agency for Toxic substances and Disease Registry), 1993). A marginally elevated occurrence of fluoride-induced osteosclerosis has been observed in workers exposed to 2.5 mg/m³ HF (equivalent to approximately 0.17 mg/kg b.w./d in a 70 kg adult). No overt signs of skeletal fluorosis or renal, hepatic or haematological effects were observed in workers exposed to 0.48 mg (total) fluoride/m³ (equivalent to 0.033 mg/kg b.w./d) for up to ten years.

Riggs *et al.* (1990) carried out a randomised placebo-controlled, double-blind clinical trial with orally-dosed fluoride in postmenopausal osteoporotic women. An increase in the rate of non-vertebral bone fractures and a decrease in cortical bone density were observed at an average intake level of 0.48 mg F⁻/kg b.w./d, administered orally as sodium fluoride for four years. However, although an increase in cancellous bone density was seen, only an insignificant trend towards a decrease in the rate of vertebral bone fractures was found.

CEPA (1993) cited various studies in which the effects of fluoride intake via drinking water were investigated. According to this review, severe skeletal fluorosis has been reported in humans after prolonged intake of 15 mg/day (0.22 mg/kg b.w. day in an adult weighing 70 kg) and above. In one case, exposure to drinking water containing 8 mg/l fluoride for 37 years resulted in fluoride-induced bone changes, but not in clinical signs. In a community exposed to 4 mg fluoride/l in the drinking water (estimated to be equivalent to 0.07 mg/kg b.w./d) the relative risk for various bone fractures was 2.2 to 2.7 as compared to an "unexposed" control community which received 1 mg/l (Sowers *et al.*, 1986). However, with respect to the latter study, CEPA (1993) stated that exposure in the high fluoride community was probably underestimated, while the calcium level in the drinking water of this community was only about 25% of that in the control group. The University of York report (McDonagh *et al.*, 2000) concludes that the findings of 29 studies on bone fracture effects show small variations around the "no effect" mark, with a meta analysis of these studies finding no association with water fluoridation.

Dental fluorosis

The only effect in humans for which there is clear evidence, at the levels of fluoride intake associated with water fluoridation, is dental (enamel) fluorosis, as indicated in a number of publications by expert groups (e.g. California EPA, 1997, US Institute of Medicine, 1999, McDonagh *et al.*, 2000.). The United States Institute of Medicine characterised dental fluorosis as a dose-response effect where fluoride ingested during the pre-eruptive development of the teeth results in changes to the structure of the enamel (US Institute of Medicine, 1999). McDonagh *et al.* (2000) state that the prevalence of dental fluorosis at a water fluoride level of 1 ppm has been estimated to be 48% (Confidence Interval (CI) 40 to 57), and for moderate dental fluorosis it was predicted to be 12.5% (CI 7 to 21.5).

In the 1930's and early 1940's Dean and co-workers carried out a series of studies on the association between exposure to excess fluoride in drinking water supplies and development of "endemic dental fluorosis" or mottled enamel in the permanent teeth (e.g. Dean, 1934, Dean *et al.*, 1935, Dean and Elvove, 1937, Dean, 1942). Dean's studies of populations of children (generally in the age range 12 - 14 years) continuously exposed throughout life to community water supplies containing varying levels of fluoride showed that the milder forms of dental fluorosis affected the permanent teeth of 10 - 12% of children where the drinking water had a fluoride concentration close to 1 mg/l. At a level of 2 mg/l 50% of individuals showed mild dental fluorosis, with a small incidence (< 5%) of moderate fluorosis (Dean, 1942).

The Dean studies showed a clear dose: response relationship between exposure to excess fluoride in drinking water supplies and development of dental fluorosis, which is also clearly characterised in the University of York Report (McDonagh *et al.*, 2000). The effect ranges from unnoticeable in mild forms through to aesthetically objectionable in moderate and severe forms. Mild dental fluorosis is characterised by opaque striations on the teeth that can merge to form small opaque patches. Patches most often occur on the cusps of the posterior teeth or on the incisor edge of the anterior teeth. The changes of mild dental fluorosis are not readily apparent to the affected individual or casual observer and are often detected only by specialist examination. However, teeth that are affected by moderate to severe dental fluorosis are characterised by changes such as brown staining and surface irregularities which are readily apparent and aesthetically objectionable.

Dean suggested that dental fluorosis in a 12 year old child merely pointed a presumptive finger to a fluoride ingestion that occurred approximately 8-11 years earlier (Dean 1942). In doing so he was reflecting the view that the formation of the permanent teeth and the fluoride concentration of the blood plasma must coincide before dental fluorosis can develop. The pre-eruptive maturation of the crowns of the anterior permanent teeth is finished by the age of 8 years and therefore factors influencing the development of dental fluorosis are of most relevance in the first 8 years of life. It is widely accepted that the most critical period for developing dental fluorosis of the permanent central incisors is between 15 - 30 months of age. Evans & Darvell (1995) suggested that this critical period lies

between 15 and 24 months for males and 21-30 months for females. They showed that peak correlation of the tooth fluorosis score for the right maxillary central incisors (incisal 3rd of the tooth) with fluoride concentration in water centered around 17.5 months after birth for males and 6 months later for females.

The majority of studies have focussed on fluorosis of the permanent dentition and its relationship with exposure to fluoride in drinking water and also other sources such as fluoride in toothpaste and fluoride supplements in early childhood. However, it is now generally accepted that exposure to fluoride in infancy and early childhood can also cause fluorosis of the primary dentition (e.g. Warren *et al.*, 1999, 2001). A number of studies have shown that fluorosis of primary teeth can be prevalent and severe in countries with regions of very high natural levels of fluoride in water, e.g. Africa and Israel. Thylstrup (1978) investigated the extent of primary tooth fluorosis in three areas of Tanzania with natural levels of fluoride in water of 3.5 mg/l, 6.0 mg/l and 21 mg/l respectively, and found that the severity of fluorosis increased in parallel with the fluoride content of the water. He observed that the posterior primary teeth, particularly the 2nd molars, were most frequently and severely affected. Olsson (1979) reported an 88% incidence of primary tooth fluorosis in Ethiopian children living in an area with a level of 3.5 mg/l natural fluoride in the water, with the incidence rising to 99% in an area with 12.4 mg/l fluoride, while Mann and co-workers (1990) reported a 30% incidence of moderate fluorosis in the primary dentition of 6 - 8 year old Israeli children living in an area with a level of 5 mg/l natural fluoride.

However, fluorosis of the primary dentition is recognised to be less prevalent and generally less severe than fluorosis of the permanent dentition in areas of optimal or suboptimal water fluoride levels (Warren *et al.*, 1999, 2001, Forsman, 1974, Thylstrup, 1978). Studies in Europe and the USA, where fluoride concentrations in water are generally below 2 mg/l, show that although fluorosis of a mild nature occurs with varying prevalence in primary teeth, anterior teeth are rarely affected and the prevalence of moderate fluorosis in primary teeth is very low. The lower prevalence of fluorosis in anterior primary teeth may be due, at least in part, to the fact that crown development in these teeth is substantially complete at birth.

Forsman (1977) reported a 0%, 43%, 50% and 76% prevalence of mild fluorosis in the primary dentition of four populations of children who had resided from birth in regions of Sweden with water fluoride concentrations of less than 0.2 mg/l, 0.8 mg/l, 1.5 mg/l or 2.75 mg/l respectively. She observed moderate fluorosis of the primary molars in 4% of the children who had resided from birth in the area with a water fluoride concentrations of 2.75 mg/l, but there was no moderate fluorosis of primary molars in the children residing in areas with water fluoride levels of less than 0.2 mg/l, 0.8 mg/l or 1.5 mg/l. Similarly, no moderate fluorosis was observed in primary teeth in children in regions of Greenland and Denmark with water fluoride levels of 1.1-1.6 mg/l (Larsen *et al.*, 1988) or in regions of the UK with water fluoride levels of 1 mg/l (Booth *et al.*, 1992; Weeks *et al.*, 1993). Warren *et al.* (2001), in a study of 637 children in Iowa exposed to fluoridated water from birth and

examined at 4.5 to 5 years, showed that 11.6% had mild fluorosis in 1 or more of their primary teeth, only 2 individuals showing any evidence of moderate fluorosis. The authors concluded that primary tooth fluorosis is relatively uncommon and is most frequently seen on posterior teeth, particularly primary second molars, which form at later stages of development.

Evans & Darvell (1995) suggested that the most critical period for developing dental fluorosis of the permanent central incisors lies between 15 and 24 months for males and 21-30 months for females. This view is supported by the work of Larsen and co-workers (1988). Larsen and co-workers compared the prevalence of fluorosis in the primary and permanent teeth of a population of children in Denmark who had been either breastfed or fed on cow's milk during the first year of life (not exposed to fluoride in reconstituted formula) with that of a population of children in Greenland who had been fed with infant formula reconstituted with fluoridated water containing 1.1 mg/l fluoride. They found that the Greenland children (exposed to fluoridated water in infancy) had a higher prevalence of fluorosis of the primary teeth, whereas the Danish children (not exposed to fluoride in water until after 1 year of life but then exposed to water with a fluoride concentration of approximately 1.5 mg/l), had a higher prevalence of fluorosis of the permanent teeth, especially of the later-forming teeth such as the premolars.

There is not uniformity of opinion on this matter however. Recent research suggests that exposure to fluoride in the first year of life may also be a significant factor affecting fluorosis of the permanent dentition (Warren *et al.*, 1999, Levy, pers. com.). In support of this there are several studies which suggest that early fluoride exposure may influence the development of fluorosis in the permanent dentition, e.g. those of Forsman (1977) and Walton & Messer (1981), who showed that infants breastfed in the first months of life showed a lower incidence of fluorosis of the permanent dentition than infants fed formula containing fluoride. Recent work by Levy (pers. com.) also suggests a relationship between primary tooth and permanent tooth fluorosis in the same individual, based on the work of Milsom *et al.* (1966), who found fluorosis of the primary 2nd molars to be significantly predictive of fluorosis in the permanent incisors (RR = 1.86, 95% CI 1.36, 2.54). However Levy indicates that the precise level or duration of fluoride ingestion that constitutes elevated risk is largely unknown for humans and the timing of the most critical period for development of permanent tooth fluorosis also has not been resolved. Warren *et al.* (1999) suggested, based on the findings of Larsen *et al.*, that sources of fluoride exposure and potential risk factors influencing the development of dental fluorosis may be different for the primary and permanent dentition. On balance the Scientific Committee has taken the view that the most critical period for developing dental fluorosis of the permanent central incisors is between 15 and 30 months.

Potential for carcinogenicity in humans

Based on epidemiological data the International Agency for Research into Cancer, IARC, (1982, 1987) concluded that "variations geographically and in time in the fluoride content

of water supplies provide no evidence of an association between fluoride ingestion and mortality from cancer in humans". This evaluation preceded the animal carcinogenicity studies carried out by NTP (1990) and Maurer (1993) described in Appendix 1. Several other organisations have reviewed the available epidemiological studies of possible relationships between exposure to fluoride via fluoridated water and cancer mortality in humans and have concluded that there is no reliable evidence of an association between consumption of fluoridated water and increased mortality due to cancer (e.g. CEPA, 1993, Janssen and Knaap, 1994). McDonagh *et al.* (2000) in the University of York Systematic Review of Water Fluoridation provided an extensive and up-to-date evaluation of the effect of water fluoridation on cancer and concluded that no association could be detected between water fluoridation and mortality from any cancer, or from bone or thyroid cancers specifically. They evaluated a total of 26 studies, meeting certain quality inclusion criteria, that had examined the association between water fluoridation and overall cancer incidence and mortality. The report indicates that bone/joint and thyroid cancers were of particular concern due to fluoride uptake by these tissues. McDonagh and co-authors reported the following:

"Four studies considered the association of bone related cancer and water fluoride exposure, performing eight analyses. Of these, the direction of association of water fluoridation and bone cancer was found to be positive in three, negative in four and one did not detect a relationship. None of the studies found a statistically significant association, however one study (Mahoney, 1991) contributed five of the nine analyses with no variance data.

Seven studies of osteosarcoma, presenting 12 analyses were included. Of these, the direction of association between water fluoridation and osteosarcoma incidence or mortality was found to be positive (fewer cancers) in seven, negative (more cancers) in three and two found no relationship. Of the six studies that presented variance data, one (Cohn, 1992) found a statistically significant association between fluoridation and increased prevalence of osteosarcoma in males. This study however, also had the lowest validity score, 2.5 out of 8. One study (Mahoney, 1991) contributed four of the 12 analyses but did not provide variance data."

McDonagh *et al.* concluded from the above analysis and from the results of the two studies (out of the 26 they evaluated) that had investigated the association of water fluoride level with cancer of the thyroid gland, that there was no clear evidence for incidence of or mortality due to bone cancers, thyroid cancer or all cancers.

Overall, the very extensive database of studies on any association between water fluoride level and incidence of or mortality from cancer in humans indicate that these data should be used in the risk characterisation for infants exposed to fluoride via reconstitution of infant formula with fluoridated water, rather than the results of animal carcinogenicity studies (see Appendix 1). Although the overall conclusion from the animal studies is that fluoride is not a carcinogenic substance in animals, equivocal evidence for induction of osteosarcomas in

males were obtained in one of the four carcinogenicity studies in rodents. The conclusion of a number of expert bodies on the human data is that these studies provide no evidence of an association between water fluoridation and cancer.

Reproductive toxicity

Human data on the reproductive toxicity of fluoride are lacking. Some Russian studies have shown slightly more stillbirths among women working in an industrial setting in a heavily fluoride-contaminated room and exposed to very high atmospheric concentrations of fluoride over a long period of time (Whitford, 2001, personal communication). However, a problem in the industrial setting is that fluoride is only one of potentially many compounds that can have adverse effects and separating out these effects is problematic.

Genotoxicity

There is no evidence of a genotoxic effect of fluoride in humans

Exposure Assessment

Introduction

Irish infants can be exposed to fluoride from a number of sources. At an early age they may be exposed to fluoride from water either directly or through formula feed (in the case of infants that are not exclusively breastfed). However as they progress through the first year of life the amount of infant formula consumed is reduced as solid foods and other drinks are introduced. Foods and drinks manufactured using Irish water are likely to contain fluoride from the water supply. Other foodstuffs such as tea contain naturally high levels of fluoride. In addition to this many parents start to brush their infant's first teeth and may or may not use fluoride toothpaste, which is inevitably swallowed to some degree by the infant. Therefore, as an infant is weaned onto a more diverse diet the sources of fluoride exposure increase.

There are currently no data in Ireland on food consumption patterns in young infants. Therefore it is not possible to estimate the total fluoride intake from all sources over the first year of life. However, with respect to the consumption of infant formula, the group of infants which would be expected to receive the greatest fluoride intake on a body weight basis would be formula-fed infants younger than 4 months. It can be reasonably assumed that the contribution of infant formula to overall fluoride intake decreases after this period. In the absence of measured consumption data a mathematical model was constructed to predict estimates of fluoride intake in very young infants.,

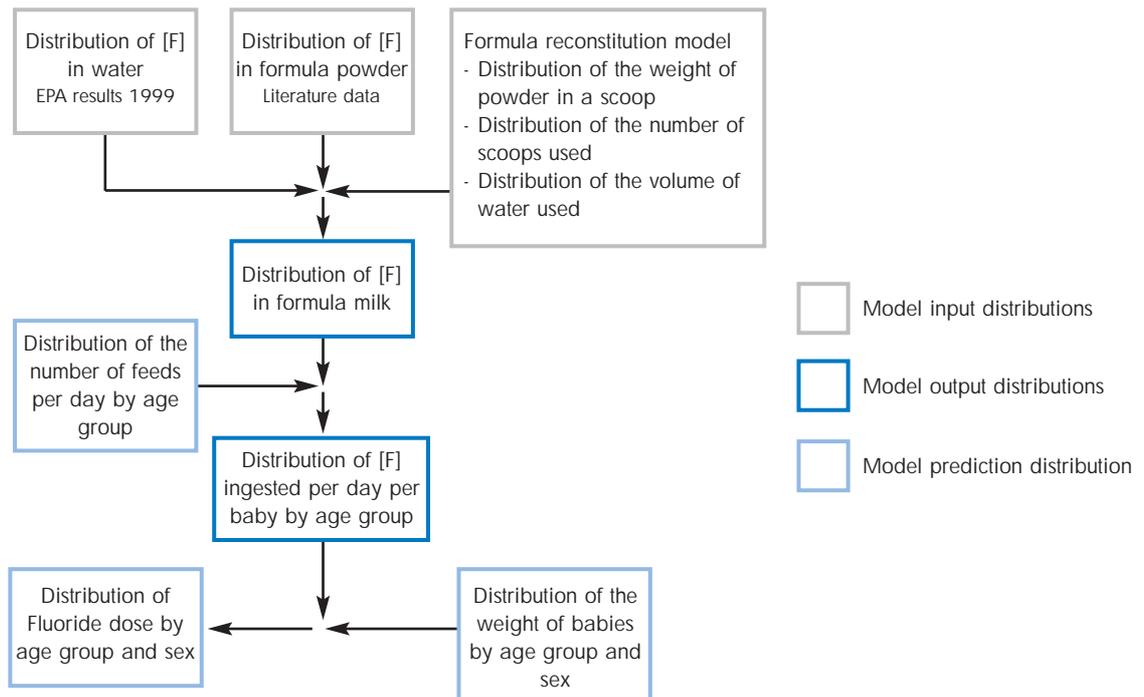
A probabilistic modelling approach was used to calculate the variation and uncertainty in the exposure of infants to fluoride from infant formula reconstituted with fluoridated water. Probabilistic modelling involves the use of distributions of data to represent the possible or measured variation in a variable that is used to calculate exposure. For example, instead of

representing the concentration of fluoride in water by a single value of 1mg/litre the concentration is represented by a range of possible values between a minimum and maximum limit. Where possible, the range and relative chance of a particular value occurring was derived from measured data. However, where measured data were unavailable values were represented by a suitable distribution based on expert opinion. The more measured data the more accurate the model. The more assumptions and expert opinion the less accurate the model. The models presented here used data in important areas but lacked data in others. Therefore, the resulting estimates of fluoride intake are considered close to the true dose but are not definitive. The models could be improved with data on feeding practices or actual volumes of infant formula consumed by babies in this age group.

Two models were produced. The first model examined the range of possible daily fluoride exposures on any one day, given the variation in fluoride water measurements in Ireland. The second model examined the average daily exposure to fluoride of babies fed exclusively on formula over the first 4 months of life. Fluoride exposure was expressed on a per body weight per day basis. The models were created and simulated using @Risk (Palisade™) using a Monte Carlo approach with a random seed across three simulations using 10000 iterations for each simulation. The simulations were monitored for convergence and all simulations converged. No significant differences were identified in the input or output statistics for each simulation. Hence the models were considered robust.

Model 1: Variations in fluoride exposure on any single day

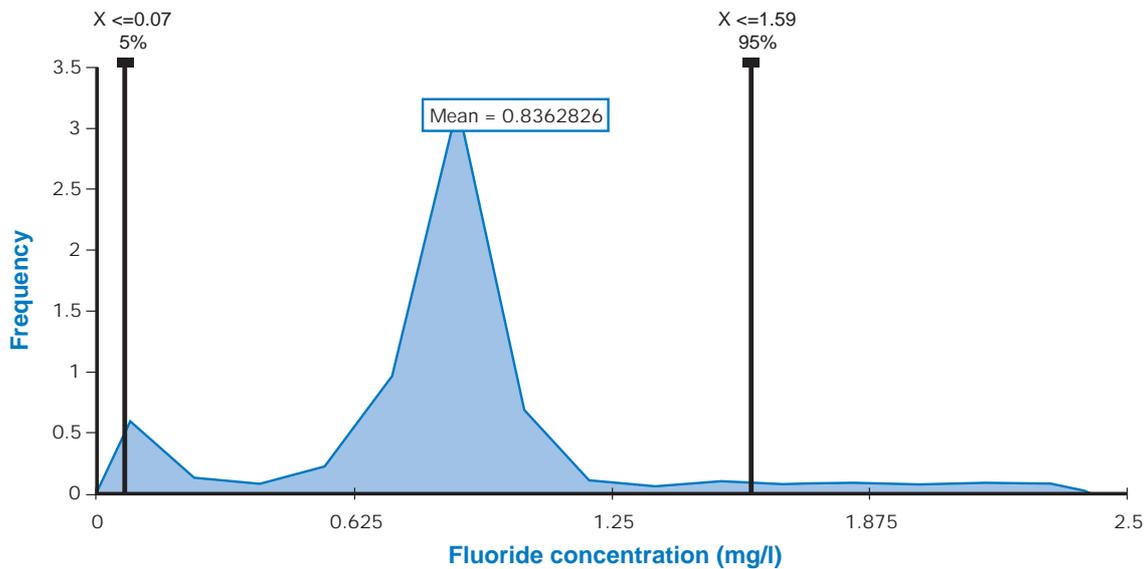
Figure 1 shows the schematic for the development of the acute exposure model.



Module 1: Estimation of the fluoride concentration of water

The latest data available on the concentrations of fluoride in Irish water supplies at the time of modelling were reported by the Environmental Protection Agency in 2000. The EPA supplied the raw data represented in their 2000 report, although data were missing for the four Dublin supplies. However, an EPA expert advised that for the Dublin supplies the data from 1998 and 1997 would be representative of the 1999 values (Dr. P. Flanagan). Therefore the 1998/97 data for Dublin was merged with the 1999 data for all other regions to give a data set of 4270 measurements of fluoride levels in the tap water provided by 387 water supplies. These data were represented as a cumulative distribution. Figure 2 shows the results of the Monte-Carlo sampling from this distribution across 10,000 iterations.

Figure 2 Distribution of possible fluoride concentrations in Irish tap water on any single day

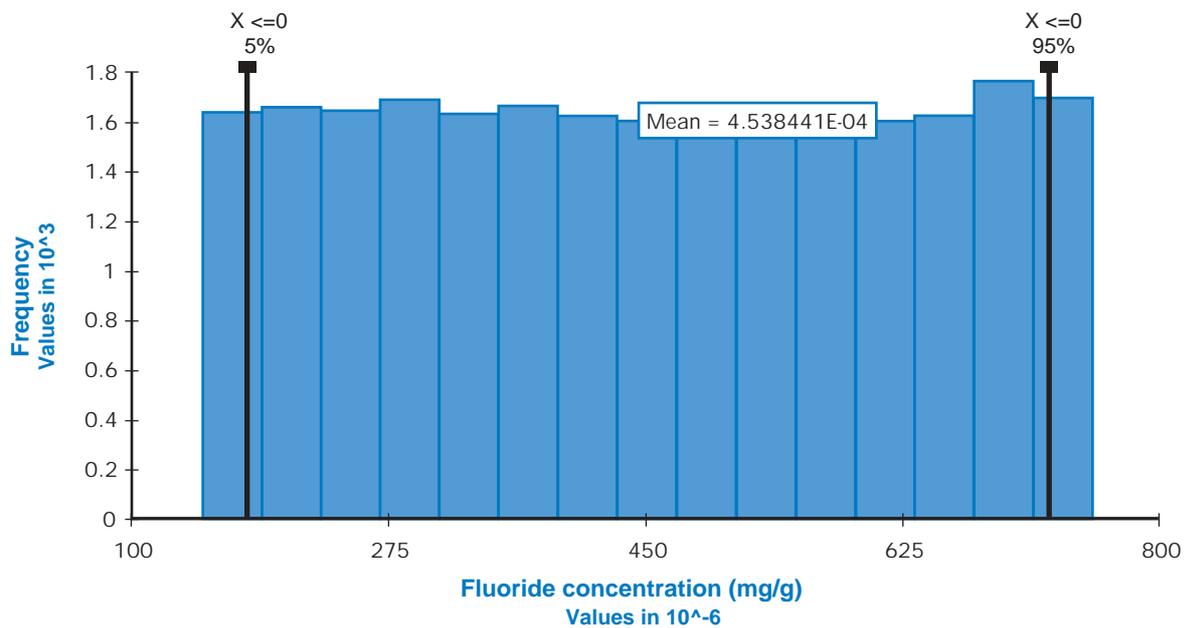


Module 2: Estimate of fluoride concentration in infant formula powder

The infant formula manufacturers in Ireland were approached for data on the fluoride concentration of infant formula powder. The data received were insufficient to allow a distribution to be fitted to them. However, the data were used to ensure the estimates that were used were realistic. The literature was reviewed to identify suitable studies that reported fluoride concentrations in infant formula powders. A study completed in the UK was selected as the most likely study to represent the situation in formula powders on the Irish market. The study measured fluoride concentrations in 6 samples of powdered formula brands reconstituted with distilled water. The study reported a detection limit of 0.01mg/kg

and a measurement error of 8% (Vlachou *et al.*, 1992). It reported a range of fluoride concentrations from 0.16 to 0.70 mg/kg powder but did not report the average concentration. Therefore the data were represented by a uniform distribution with a lower limit of 0.16mg/kg minus 8% measuring error and an upper limit of 0.7mg/kg plus 8% measuring error. In a uniform distribution all values between the limits are equally likely. The input distribution was expressed as mg fluoride per gram of powder concentrate. Figure 3 shows the results of the Monte-Carlo sampling from this distribution across 10000 iterations.

Figure 3 Distribution of possible fluoride concentrations in infant formula powder



Module 3: Estimate of infant formula consumption patterns

Irish infant feeding guidelines do not recommend the introduction of solid foods to infants before 16 weeks (FSAI, 1999). Although it is recognised that in practice infants are often weaned earlier than 16 weeks there are no data or studies that were identified that would allow quantification of all sources of food intake in infants. In Ireland, food consumption data exist for adults (FSPB, 2001; SLAN, 1999) however, no study exists for infants. Following discussions with the UK FSA it was also established that no food consumption studies existed in the UK for the age group less than 6 months. Therefore it was not possible to utilise UK data and assume similarities with Irish infant feeding practices. Consequently it was impossible to quantify the amount and type of solid foods and non-infant formula drinks that were consumed by the under 4 month age group. Neither was it possible to quantify the amount of breast milk consumed by infants in the case of babies that may be slowly moved from breast feeding to bottle feeding in the first 4 months of life. Therefore the following assumption was made for the exposure assessment:

- **ASSUMPTION: The sole source of nutrition for infants under the age of four months was infant formula.**

In the absence of recorded consumption patterns in Irish infants, consumption was modelled based upon the manufacturers' feeding instructions. All manufacturers provide a guideline to feed reconstitution and frequency of feeds for infants, based on birth weight. Analysis of the feeding guidelines for SMA, Farley's and HIPP infant formulas demonstrated that manufacturer instructions were essentially the same. They categorised babies on approximate age and weight. For the purposes of the model, four of the age categories were chosen; birth, 2 weeks, 2 months and 4 months. For each age category the instructions gave the volume of boiled water and the number of scoops of powder that should be added to the boiled water to reconstitute the feed. Similarly the instructions recommend the number of feeds in 24 hours for each age category. In general expert opinion would suggest that most parents over feed rather than under feed their babies. Therefore it is more likely that parents will add more powder than recommended to a given volume of water (Bennett and Gibson, 1990). Parents may also feed a greater volume of formula than recommended but babies who may not consume all the formula that they are presented with could offset this influence. Similarly parents would tend toward delivering an extra feed than recommended rather than omit a feed. No data was identified that could quantify these factors, however, they all represent uncertainty in the model and must be accounted for. The only way to account for these uncertainties was by applying assumptions to the input variables. The following series of assumptions were made to describe the uncertainty.

- **ASSUMPTION: Parents measuring out water for infant formula were most likely to follow manufacturers' instructions but may have, from time to time, used 1floz (28ml) more or 1floz (28ml) less. Both were less likely events than following the manufacturers' instructions.**
- **ASSUMPTION: Parents measuring out powder for infant formula were most likely to follow manufacturers' instructions but may have, from time to time, used 1 scoop more or 1 scoop less.**
- **ASSUMPTION: Parents feeding infant formula were most likely to follow manufacturers' instructions regarding the number of feeds per day but may have, from time to time administered an extra feed or omitted a feed. However both were less likely events than following the manufacturers' instructions and the tendency to add one more feed was in turn more likely than the tendency to add one less feed.**

The water volume used to make up infant formula was represented using a pert distribution with a most likely value set at the volume of water recommended by the manufacturer, a minimum value set at this mean less 28ml and a maximum value set at this mean plus 28 ml. The weight of powder per scoop was represented with a pert distribution with a most likely value of 4.6g, a minimum value of 4.4g and a maximum value of 4.8g based on

expert paediatric opinion. The number of scoops of powder that would be used was represented by a pert distribution with a most likely value set at the number of scoops recommended by the manufacturer, a minimum value set at one less scoop than recommended and a maximum value set at one more scoop than recommended. In addition there is a clear positive correlation between the volume of water used and the number of scoops of powder. This magnitude of this correlation could not be based on data. Therefore the following assumption was used.

- **ASSUMPTION: The amount of water used and the number of scoops of powder were not independent variables. Their interdependency was described using a correlation coefficient of 0.8. This value was selected after an examination of the distribution of formula concentrations for unrealistic predictions when different correlation coefficients were substituted in the model.**

The use of the correlation coefficient ensured that when the volume of water was high the number of scoops of powder was also high, but not all the time. Finally the number of feeds in a 24 hour period was represented by a discrete distribution with a most likely value set at the number of feeds recommended by the manufacturer, a minimum value set at one less feed than recommended and a maximum value set at one more feed than recommended. However, to take account of the tendency towards following manufacturers' instructions, these values were also assigned probabilities. The most likely value was assigned a probability of 0.9 (90% of occasions) the minimum value was assigned a probability of 0.05 (5% of occasions) and the maximum value was assigned a probability of 0.05 (5% of occasions). If reports are identified that have quantified these aspects of infant feeding practice the probabilities and upper and lower values of these distributions could and should be reassigned.

For a given iteration of the model a volume of water was selected from the assigned water distribution described above and multiplied by the value for the number of feeds in 24 hours selected from the assigned feeding distribution as described above. This returned a value for the volume of water ingested in 24 hours. The calculation was carried out for each of the four age categories described earlier.

For a given iteration of the model a weight of powder per scoop was selected from the assigned scoop weight distribution described above and multiplied by the value for the number of scoops selected from the assigned scoop number distribution described above. This weight of powder was then multiplied by the value for the number of feeds in 24 hours selected from the assigned feeding distribution as described above. This returned a value for the weight of infant formula powder ingested in 24 hours. The calculation was carried out for each of the four age categories described earlier.

NB. Prior to selecting this calculation approach an alternative approach was investigated. Here each feeding event was simulated independently and the volume of water and the weight of powder calculated at each feeding event were summed to give the water volumes and powder weights for a 24 hour period. When the results of this approach were

compared to the results of the more simple approach selected there was no significant difference in the outcome. Therefore the simple approach described in detail above was selected.

Table 1 shows the results of the consumption simulation by age group. Figures 4 and 5 show the distributions of values for the 2 week age category. These are shown so that the shape of the distributions can be visualised and show similar shapes to the distributions in the other age categories.

Table 1: Results of the infant formula estimated consumption simulation

Age category	Volume of water consumed l/day/baby			Weight of powder consumed g/day/baby		
	Min	Mean	Max	Min	Mean	Max
Birth	0.347–0.351	0.513–0.514	0.755–0.779	54.72–55.64	83.41–83.55	123.33–126.69
2 Weeks	0.526–0.529	0.695–0.696	0.981–0.995	82.1–82.53	111.35–111.47	158.38–161.10
2 Months	0.713–0.718	0.858–0.859	1.158–1.175	112.41–114.2	139.38–139.69	190.98–192.28
4 Months	0.863–0.866	1.010–1.011	1.344–1.351	135.66–136.37	162.52–162.85	219.84–222.32

*range of values returned over 3 simulations of 10,000 iterations

Figure 4 Distribution of possible volumes of water consumed by a 2 week old baby on any single day as a result of consuming infant formula

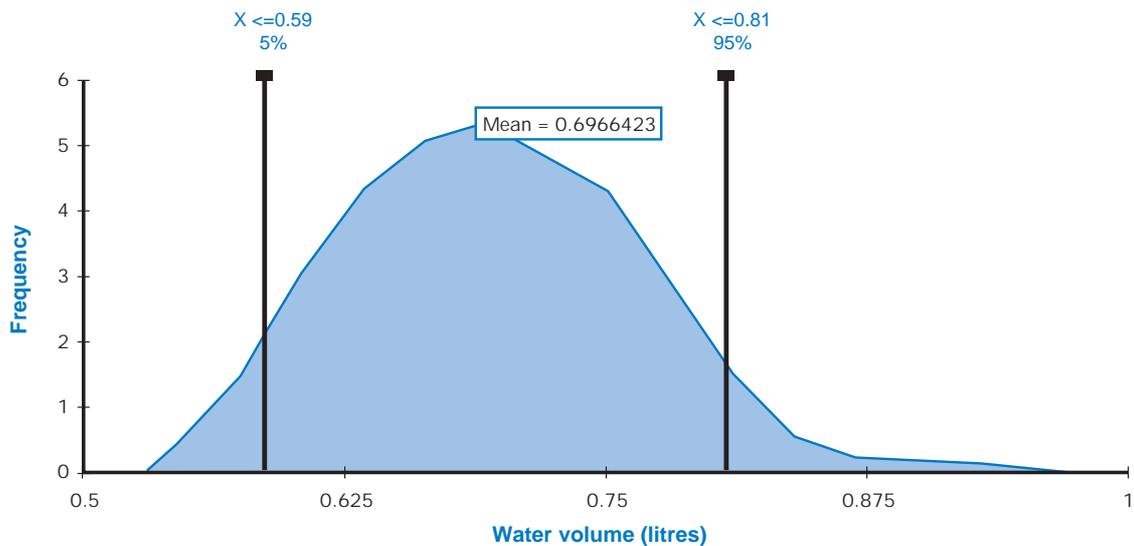
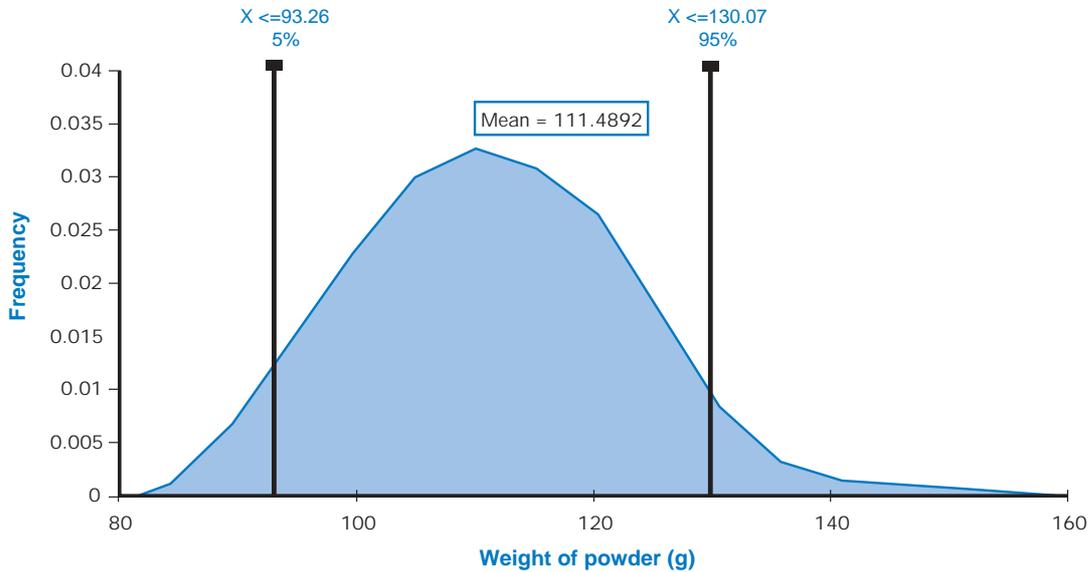


Figure 5 Distribution of possible weights of infant formula powder consumed on any single day by a 2 week old baby



Module 4: Estimate of the potential daily concentration of fluoride consumed by a baby from drinking infant formula

The outputs of modules 1 to 3 were combined to calculate the amount of fluoride consumed by a baby per day.

For each iteration of the model a value for the volume of water consumed in 24 hours by a baby selected from the volume distribution in module 3 was multiplied by a value for the fluoride concentration of water selected from the distribution calculated in module 1. Over 10,000 iterations this procedure returned a distribution of fluoride intake per baby per day resulting from water ingestion.

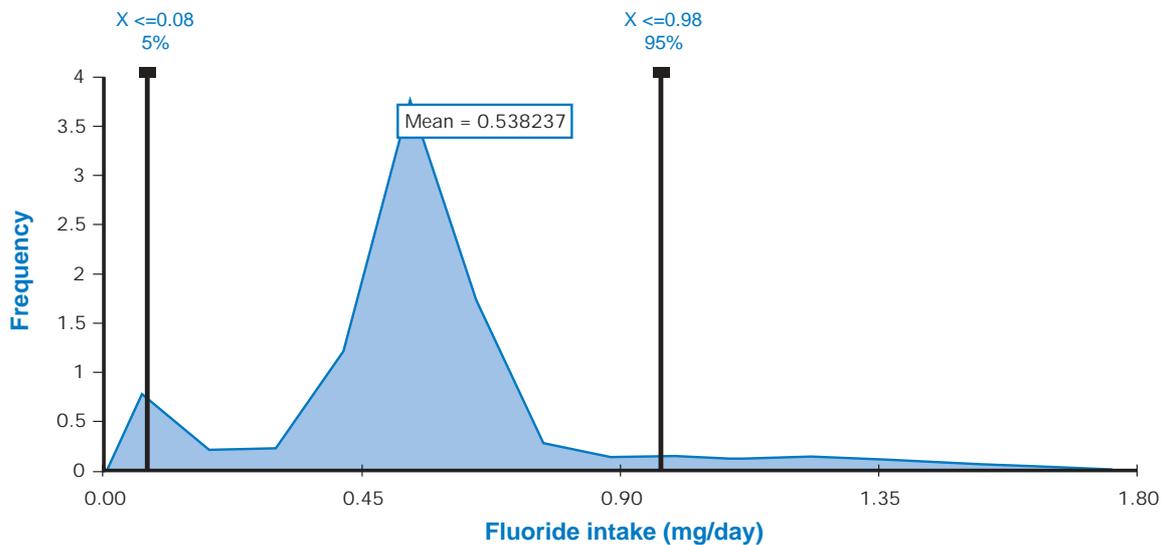
For each iteration of the model a value for the weight of formula powder consumed in 24 hours by a baby selected from the powder weight distribution in module 3 was multiplied by a value for the fluoride concentration of infant formula powder selected from the distribution calculated in module 2. Over 10,000 iterations this procedure returned a distribution of possible fluoride intakes per baby on any single day resulting from infant formula ingestion. The values were then adjusted for bioavailability. Studies carried out by Prof Denis O'Mullane suggest that 15% of fluoride is bound as calcium fluoride in infant formula (pers. comm.). Calcium fluoride is not available for absorption into the body, therefore the calculated fluoride concentrations were reduced by 15%. This calculation was carried out for each of the four age categories selected. Table 2 shows the results of the calculation and Figure 6 shows a typical distribution shape, which is bimodal due to the bimodal shape of the distribution for fluoride concentration in tap water.

Table 2: range of the possible fluoride intake in any single day for babies under 4 months of age

Age group	Concentration of Fluoride ingested (mg/day/baby)		
	Mean	5th percentile	95th percentile
Birth	0.398–0.399*	0.059–0.063	0.706–0.719
2 Weeks	0.537–0.541	0.081–0.084	0.951–0.993
2 Months	0.663–0.668	0.101–0.102	1.185–1.241
4 Months	0.779–0.785	0.118–0.122	1.396–1.472

* range indicates values for 3 simulations of 10,000 iterations

Figure 6 Distribution of possible fluoride intakes on any single day by a 2 week old baby as a result of consuming infant formula reconstituted with fluoridated tap water



Module 5: Estimate of infant body weights

Infant body weight charts are published and used by paediatricians to assess the development of babies. For this model the body weight chart was used to estimate the mean and standard deviation of the body weight at each age category selected previously (Child Growth Foundation, 1995). It was assumed that the charts were calculated using normal distributions as is common practice for growth statistics. The distribution of weights for girls and boys in each age category was calculated using a normal distribution with a

mean and standard deviation estimated from the growth chart. Table 3 shows the means and standard deviations for the normal distribution of body weight for boys and girls in each age category.

Table 3: statistical values used for estimating body weight of infants

Age	Boys weight (kg)		Girls weight (kg)	
	Mean	Std deviation	Mean	Std deviation
Birth	3.6	0.45	3.5	0.29
2 Weeks	4	0.71	3.9	0.4
2 Months	5.4	0.47	5.3	0.4
4 Months	7	0.57	6.7	0.46

Model Output: Estimate of fluoride intake resulting from the consumption of infant formula reconstituted with fluoridated water in Ireland

Intake is traditionally expressed on a per body weight basis. Therefore, the total concentration of fluoride ingested by a baby per day must be divided by its body weight to calculate the intake per kg bodyweight.

For each iteration of the model a value for the concentration of fluoride ingested by a baby per day selected from the calculated distribution in module 4 was divided by a value for the baby's weight selected from the distribution calculated in module 5. Over 10000 iterations this procedure returned a distribution of possible fluoride intakes per kg body weight on any single day resulting from ingestion of infant formula reconstituted with fluoridated water.

Table 4a shows the range of possible fluoride intakes for baby BOYS in each age category as a result of the reconstitution of infant formula with fluoridated water. Table 4b shows the range of possible fluoride intake for baby GIRLS in each age category as a result of the reconstitution of infant formula with fluoridated water. Figure 7 shows a typical distribution shape.

Table 4a : estimated range of fluoride intakes in baby boys on any single day

Age	Statistics of the estimated fluoride intake (mg/kg b.w./day)		
	Mean	5th percentile	95th percentile
birth	0.112-0.113*	0.016-0.018**	0.201-0.204
2 weeks	0.139-0.140	0.020-0.021	0.255-0.259
2 months	0.123-0.125	0.018-0.019	0.220-0.231
4 months	0.112-0.113	0.017-0.018	0.196-0.209

*range across 3 simulations of 10,000 iterations

**same value returned in all 3 simulations

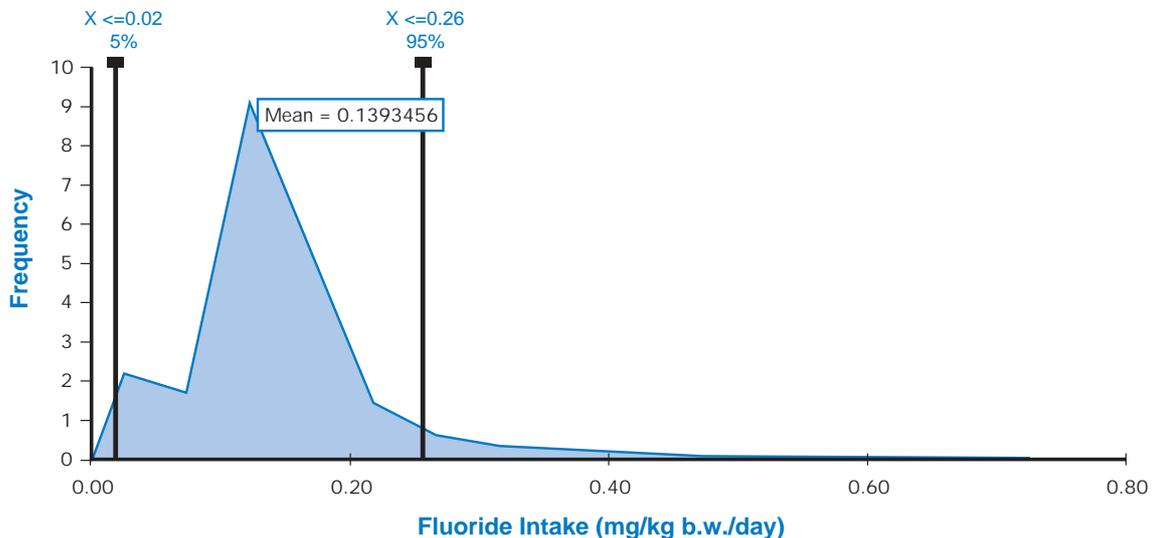
Table 4b: estimated range of fluoride intakes in baby girls on any single day

Age	Statistics of the estimated fluoride intake (mg/kg b.w./day)		
	Mean	5th percentile	95th percentile
birth	0.114-0.115*	0.016-0.018	0.200-0.207
2 weeks	0.139-0.140	0.020-0.021	0.246-0.256
2 months	0.126-0.127	0.019-0.020	0.223-0.231
4 months	0.117-0.118	0.017-0.018	0.207-0.218

*range across 3 simulations of 10,000 iterations

**same value returned in all 3 simulations

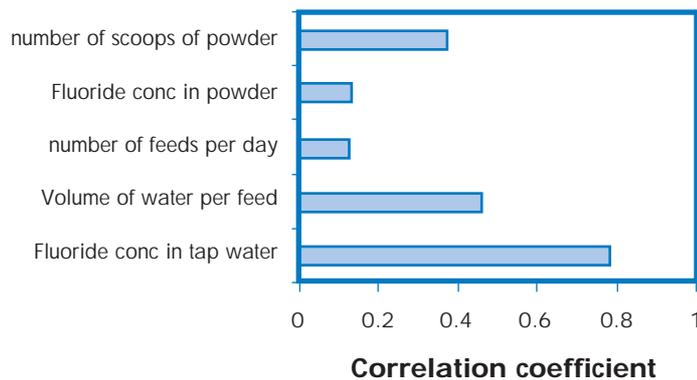
Figure 7 Distribution of possible fluoride intakes on any single day for male babies at 2 weeks of age expressed on a body weight basis resulting from the consumption of infant formula reconstituted with fluoridated tap water



Comments on Model 1

Analysis of the sensitivity report produced by @Risk for the model simulation described in this report demonstrated that the greatest influence on the estimate of fluoride intake in babies on any single day was the concentration of fluoride in the drinking water. Figure 8 shows a tornado plot of the regression sensitivities of the calculated daily intake to the model input variables.

Figure 8 Sensitivity analysis for fluoride exposure assessment



The estimate was also influenced, to a lesser extent, by the volume of water consumed per feed. The concentration of fluoride in the infant formula powder only had a small influence on the daily fluoride intake for babies. Hence, any measure directed at reducing fluoride concentrations in infant formula is unlikely to influence the fluoride intake of babies.

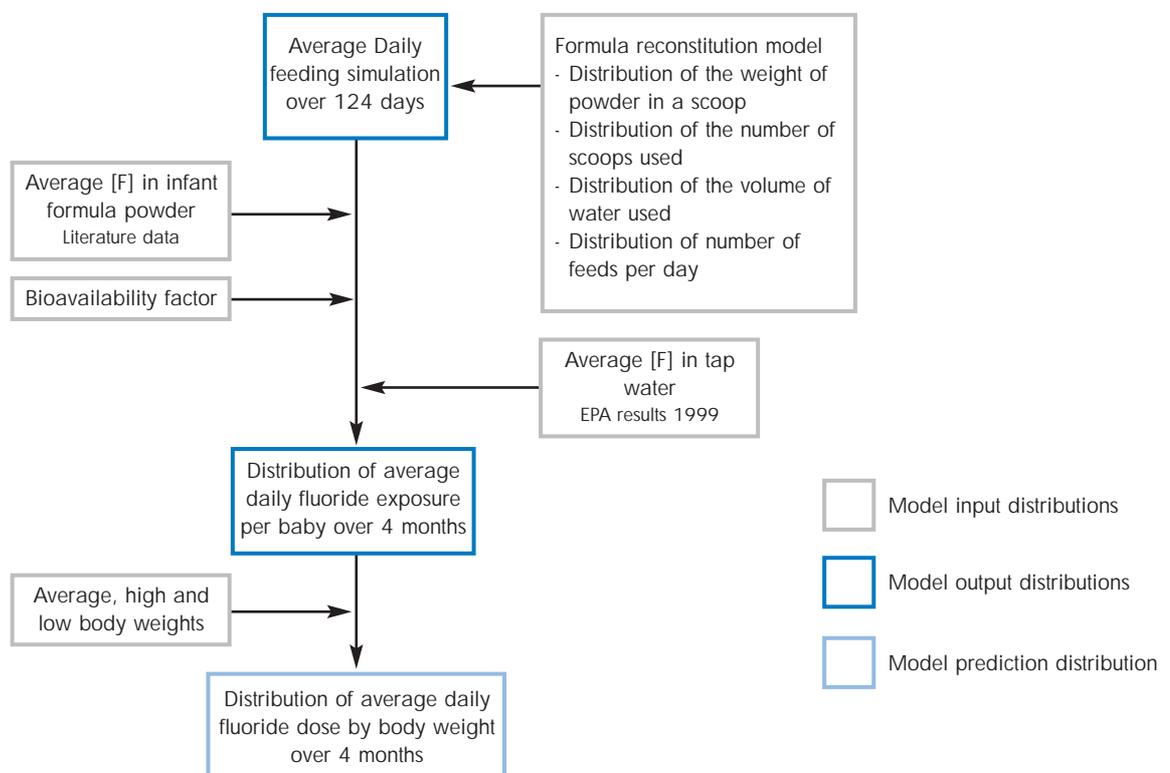
The estimate of the concentration of fluoride in drinking water is based on data from the EPA and is therefore a reasonable estimate of the true fluoride concentration of drinking water. It should be noted that the range of values for fluoridation of the water supply was far more varied than expected with many values below 0.8mg/l and two values higher than 3mg/l. Hence the cumulative distribution showed a bimodal effect with a small subset of fluoride concentrations represented by values between 0 and 0.2 mg/l. The shape of this distribution greatly influenced the shape of the distribution of intake. Hence a small number of predicted intakes on any single day (5%) were above 0.259mg/kg b.w./day in some cases.

A more accurate estimate of the true fluoride intake on any single day could be gained by a more accurate estimate of infant feeding practice and in particular the volumes of formula consumed in a 24-hour period. The most likely estimates for the infant feeding variables are, however, based on manufacturers' instructions and therefore it is likely that these are reasonable estimates of the true value for each variable. The level of supervision and instruction in maternity hospitals and the work of the public health nurses in educating parents on the correct procedures for infant feeding continually emphasise following manufacturers' instructions. The uncertainty in the estimate of feeding practice is influenced by the assumptions used to define it. However, given the overriding influence of the fluoride content of the water on the final estimate of acute intake, changes in these assumptions would have a lesser influence on the final estimate of acute intake.

Model 2: Variations in average fluoride intake during a four month period

For this kind of exposure assessment it is important to examine the average daily intake over the 4 month period rather than examine changes in the daily intake on any single day (see model 1). The model was developed as a variation of model 1, utilising the same assumptions but taking averages of some input variables rather than a distribution of all possible values. The model schematic is shown in figure 9.

Figure 9: Chronic exposure model schematic

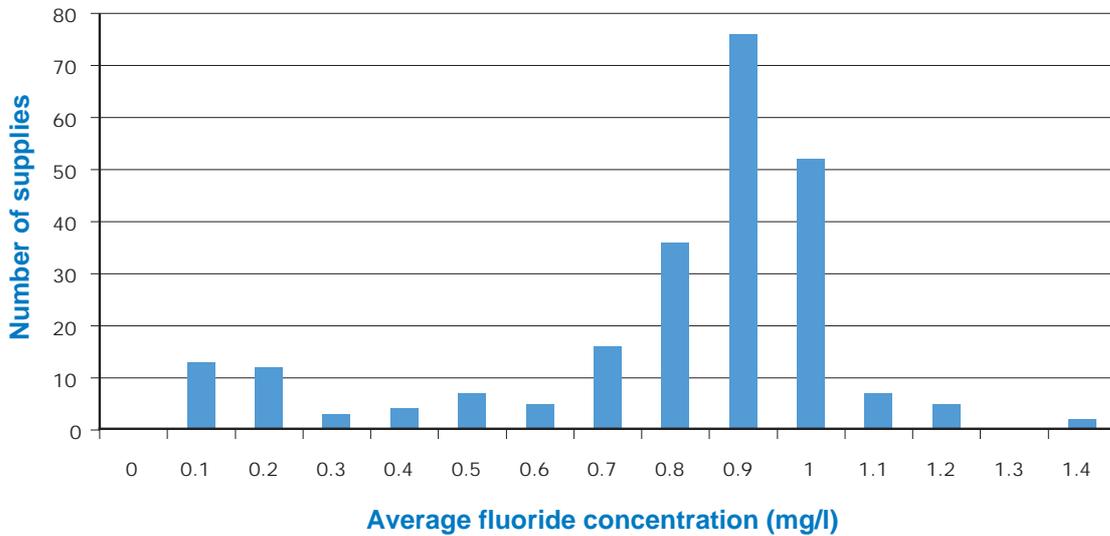


Module 1 Average fluoride concentration of tap water

The latest data available on the concentrations of fluoride in Irish water supplies at the time of modelling were reported by the Environmental Protection Agency in 2000. The EPA supplied the raw data represented in their 2000 report, although data were missing for the four Dublin supplies. However, an EPA expert advised that for the Dublin supplies the data from 1998 and 1997 would be representative of the 1999 values (Dr. P. Flanagan). Therefore the 1998/97 data for Dublin was merged with the 1999 data for all other regions to give a data set of 4270 measurements of fluoride levels in the tap water provided by 387 water

supplies. All values of zero were removed since these corresponded to equipment downtime (Dr. P. Flanagan, pers. com.) and an average fluoride concentration was calculated for each of these 387 supplies. For some supplies a statistically meaningful average could not be calculated because sufficient data was lacking. These supplies were excluded from the final data set. This process resulted in the calculation of average fluoride concentrations for 238 supplies. Figure 10 shows the distribution of average fluoride concentrations for water from these supplies in 1999.

Figure 10 Average yearly fluoride concentration of regional water supplies



Analysis of these data revealed that the median average fluoride concentration was 0.845mg/l with a 95th percentile value of 1.03mg/l. Therefore the 95th percentile value was used in the exposure model, i.e. it was based on the premise that 95% of regional water supplies had average fluoride concentrations below 1.03mg/l.

Module 2: Average fluoride concentration of infant formula powder

A study completed in the UK was selected as the most likely study to represent the situation in formula powders on the Irish market. The study measured fluoride concentrations in 6 samples of powdered formula brands reconstituted with distilled water. The study reported a detection limit of 0.01mg/kg and a measurement error of 8% (Vlachou *et al.*, 1992). It reported a range of fluoride concentrations from 0.16 to 0.70 mg/kg powder but did not report the average concentration. Therefore the central value of the range, 0.43mg/kg, was chosen to represent the average fluoride concentration of infant formula powder.

Module 3: Estimate of infant formula consumption patterns

The model required the calculation of average volumes of water and average weights of infant formula powder consumed during a four month period. The same approach was used as described previously in module 3 of model 1. However, here the simulation was created for each day of the four month feeding period assuming 31 days in each month (or a total of 124 days feeding). Each days feeding was independent of all other days. Hence the model calculated 124 average daily values for water and powder intake. These values were averaged to provide an average daily volume of water consumed by a baby each day of the four month period and an average daily weight of infant formula powder consumed by a baby each day of the four month period. Hence over 10,000 iterations a distribution for each of these average values was calculated. Table 5 shows the values for the distributions calculated.

Table 5: Distribution of average values for daily water and infant formula powder consumption

Volume of water consumed l/day/baby			Weight of powder consumed g/day/baby		
5th percentile	Mean	95th percentile	5th percentile	Mean	95th percentile
0.747 **	0.757 **	0.767 **	118.55–118.57	122.23–122.28	125.92–125.96

** same result to 3 decimal points returned across three simulations

Module 4 : Estimate of the average daily concentration of fluoride consumed by a baby from drinking infant formula over a 4 month period

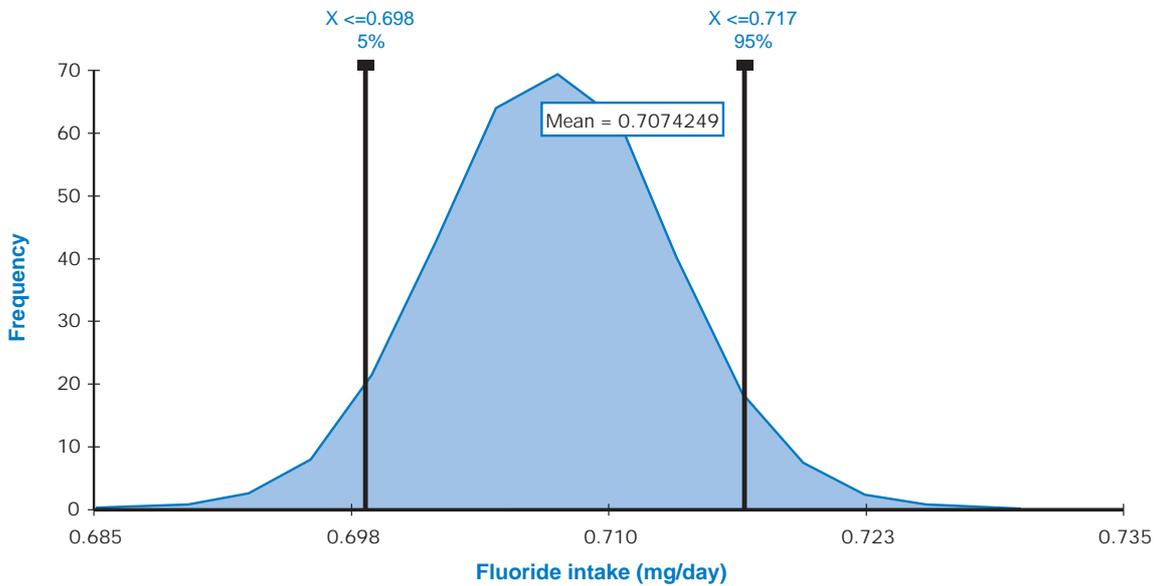
The average exposure of a baby to fluoride from infant formula reconstituted with fluoridated tap water was calculated over a four month period. The 95th percentile value for the average fluoride concentration of regional tap water supplies (module 1) was multiplied by values from the distribution of average daily consumption of water (module 3). The average fluoride concentration of infant formula powder (module 2) was multiplied by values from the distribution of average daily consumption of infant formula powder (module 3). The sum of these two values was multiplied by the bioavailability factor of 0.85 (described in module 4 of model 1 described previously). Table 6 shows the range of values of the distribution across 10,000 iterations. Figure 11 shows the distribution shape.

Table 6: Range of the estimated average daily fluoride intakes for babies under 4 months of age

Concentration of Fluoride ingested (mg/day/baby)		
Mean	5th percentile	95th percentile
0.700**	0.698**	0.717**

* values for 3 simulations of 10,000 iterations

Figure 11 Distribution of possible average daily intakes of fluoride by babies consuming infant formula reconstituted with fluoridated water during the period from birth to 4 months of age



Module 5: Estimate of average infant body weights over the first four months of life

Infant body weight charts are published and used by paediatricians to assess the development of babies. For this model the body weight chart was used to estimate the mean and standard deviation of the body weight at each age category selected previously (Child Growth Foundation, 1995). The charts were used to determine the mean, 2nd percentile and 98th percentile body weight for infants from 0 to 4 months old. From these values an average body weight for the four month period was calculated for the three categories of baby; low weight (2nd percentile), average weight (mean) and high weight (98th percentile).

Model Output: Estimate of average daily fluoride intake from the consumption of infant formula during the first four months of life.

Intake is traditionally expressed on a per body weight basis. Therefore, the total average concentration of fluoride ingested by a baby per day must be divided by its average body weight to calculate the intake per kg body weight.

Appendix 18 Risk assessment of the fluoride intake of Irish infants under 4 months of age as a result of the consumption of infant formula re-constituted with fluoridated water

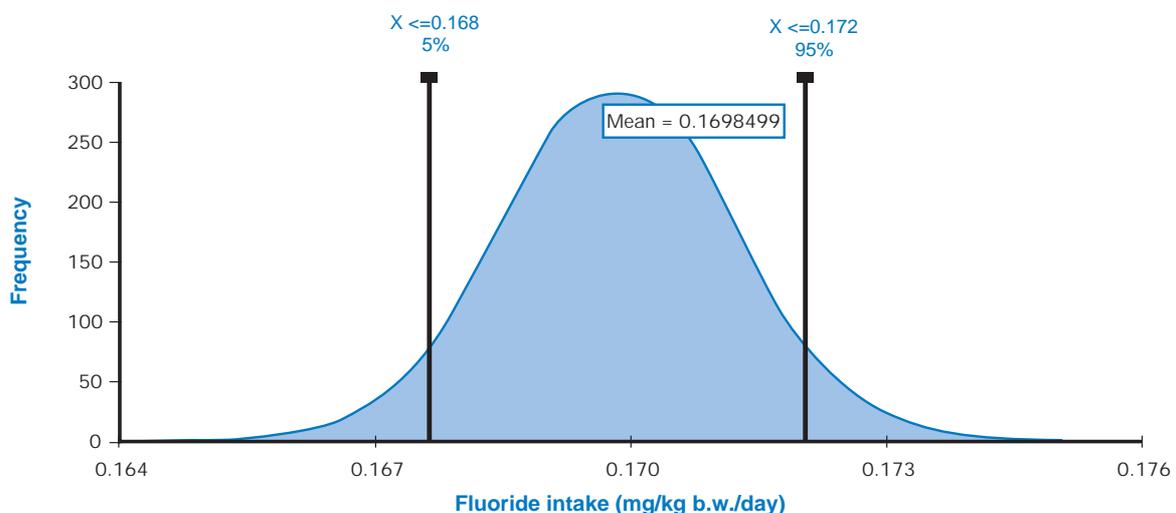
For each iteration of the model a value for the average concentration of fluoride ingested by a baby per day selected from the calculated distribution in module 4 was divided by the average body weight of a low, average and high weight baby calculated in module 5. Over 10,000 iterations this procedure returned a distribution of average fluoride intakes per kg body weight per day resulting from ingestion of infant formula reconstituted with fluoridated water over the first four months of life. Table 7 shows the range of values for the estimate. Figure 12 shows a typical distribution for the possible average daily fluoride intakes for low weight babies.

Table 7:

Average body weight of baby 0-4 months of age	Average daily Fluoride intake over 4 months (mg/kg b.w./day)		
	5th percentile	mean	95th percentile
Low	0.168**	0.170**	0.172**
Average	0.131**	0.132**	0.134**
High	0.105**	0.106**	0.108**

** same value to 3 decimal points returned across 3 simulations

Figure 12 Distribution of possible average daily fluoride intakes relative to body weight for low weight babies consuming infant formula reconstituted with fluoridated tap water during the period from birth to 4 months of age



Risk Characterisation

Discussion of the exposure assessment findings

Estimates were made of fluoride intake in exclusively formula-fed infants aged 0-4 months as a result of both acute and chronic exposure, using accepted norms for daily volume of infant formula consumption and body weight standards, together with measured values for fluoride content of water reported by the Environmental Protection Agency. The water fluoride data showed that although some water regions reported considerable variation in fluoride measurements during the year, 95% of supplies achieved a yearly average measured water fluoride concentrations below 1.03mg/l. The statutory upper limit in Ireland is 1mg/l. The remaining 5% of supplies exceeded the statutory limit on a consistent basis, however the highest average fluoride concentration calculated in any of these non-compliant supplies was 1.35mg/l.

The mean fluoride intake on any single day in infants aged 0 - 4 months ranged from 0.112 to 0.140mg/kg b.w./day depending on age group, with the 95th percentiles ranging between 0.196 and 0.259mg/kg b.w./day. These predicted intakes were well below the intakes of fluoride associated with acute toxic effects, which are in the range of 50-100mg/kg b.w./day. Therefore there is no risk of acute fluoride toxicity to infants resulting from the consumption of infant formula reconstituted with fluoridated tap water

The maximum average intake of fluoride from infant formula reconstituted with fluoridated tap water over the first four months of life was estimated to be in the range 0.105mg/kg b.w./day to 0.172mg/kg b.w./day, depending on body weight. This intake was calculated for infants residing in areas served by the 95% of water supplies that achieved an average yearly water fluoride level of below 1.03 mg/l. These predicted levels related to daily consumption by a single infant each day during the full four month period of concern and only concerned exposure from infant formula rather than any additional sources of fluoride.

The exposure of infants to fluoride because of the reconstitution of infant formula with fluoridated tap water has been recognised in other studies. Levy *et al.* (1995) studied the fluoride intake of infants based on three day beverage and food diaries completed by mothers in Iowa, USA. They found that for infants 6 weeks of age the mean intake was 0.14mg/day with a 90th percentile of 0.83mg/day. Similarly for infants aged 3 months they found a mean intake of 0.14mg/day and a 90th percentile intake of 1.06mg/day. Another study in Iowa, USA, estimated fluoride intakes in infants less than three months to range between 0.66mg/day and 0.79mg/day when tap water was fluoridated at a level of 1mg/l (Adair and Wei, 1978). These values are similar to those predicted in this study, where intakes were estimated to range between 0.698-0.717mg/day

Discussion of the hazard characterisation findings

There is an extremely large epidemiological database on human response to a low intake of fluoride from tap water. It has been accepted by many expert groups at an international level which have reviewed these data that there is no substantive evidence that fluoride intakes in the range predicted for young infants by the exposure modelling in this risk assessment are associated with adverse health effects other than enamel fluorosis (e.g. Thiessen, 1988, CEPA, 1993, Janssen and Knaap, 1994, California EPA, 1997, US Institute of Medicine, 1999, McDonagh *et al.*, 2000,). The adverse effects observed in animal studies, as summarised in the hazard characterisation section of the risk assessment and described in more detail in Appendix 1, are not considered relevant for the purposes of the risk assessment, since extensive epidemiological studies have not produced evidence that the findings in animals can be extrapolated to human populations drinking fluoridated water over many years (e.g. California EPA, 1997, US Institute of Medicine, 1999, McDonagh *et al.*, 2000,). It is therefore considered more appropriate to base the risk characterisation on the available human data, rather than the animal data.

It is recognised that fluoride intakes at levels obtained from fluoridated tap water may contribute to fluorosis of dental enamel, a dose: response effect caused by fluoride ingestion during the pre-eruptive maturation of teeth (Dean 1934). In its mild form, dental fluorosis has no effect on tooth function and may render the enamel more resistant to caries (US Institute of Medicine, 1999). Mild dental fluorosis is characterised by opaque striations on the teeth that can merge to form small opaque patches. Patches most often occur on the cusps of the posterior teeth or on the incisor edge of the anterior teeth. The changes of mild dental fluorosis are not readily apparent to the affected individual or casual observer and are often detected only by specialist examination. However, teeth that are affected by moderate to severe dental fluorosis are characterised by changes such as brown staining and surface irregularities which are readily apparent and aesthetically objectionable. Hence, in the context of this report, the established unwanted effect considered to be associated with intakes of fluoride from fluoridated water is moderate dental fluorosis (US Institute of Medicine, 1999).

There is a lack of agreement among expert groups on the tolerable upper intake level of fluoride in young infants, in relation to dental fluorosis. The United States Institute of Medicine (US Institute of Medicine, 1999) derived a tolerable upper intake level for fluoride based on the relationship of average fluoride intake from birth to eight years of age to the prevalence of moderate dental fluorosis in permanent teeth, as established by the work of Dean (Dean *et al.*, 1937, 1942). They noted that Dean in 1942 had established that the milder forms of dental fluorosis affected the permanent teeth of 10-12% of people exposed to daily intakes of fluoride ranging from 0.02 -0.1 mg/kg b.w./day throughout the first 8 years of childhood with an average exposure of 0.05mg/kg b.w./day. This value has often been regarded as the no observable effect level (NOAEL) for dental fluorosis (Whitford, Pers. Comm.). Further, the United States Institute of Medicine noted that exposure to fluoride throughout childhood at levels between 0.08 and 0.12mg/kg b.w./day resulted in 50% of people with mild dental fluorosis and <5% of people with moderate dental fluorosis.

They reported the average exposure resulting in this effect as being 0.1mg/kg b.w./day and this was therefore identified as the LOAEL (lowest observable adverse effect level) for the development of moderate dental fluorosis. They selected an uncertainty factor of 1 based on the fact that human data was used in deriving the LOAEL and the effect was not functional. Hence by applying the uncertainty factor to the LOAEL they derived an Upper Tolerable Intake Level (UL) of 0.1 mg/kg b.w./day.

Another expert body, the United Kingdom (UK) panel of experts reporting to the United Kingdom Department of Health, examined dietary reference values for fluoride and concluded that an intake level of 0.22mg/kg b.w./day was safe for infants up to 6 months (UK Department of Health, 1994) based on the absence of moderate dental fluorosis in children fed as infants with infant formula reconstituted with tap water containing fluoride at a concentration of 1 mg/l. The figure of 0.22mg/kg b.w./day was based on an assumed daily fluid intake by a 1-month old infant of 200 ml/kg formula, contributing 0.2 mg/kg b.w./day fluoride, with fluoride from reconstituted feed contributing 0.02 b.w./day. Fluoride intake was estimated to fall to approximately 0.13 mg/kg b.w./day by the age of 6 months.

A third body, the British Medical Association (BMA), in their New Guide to Medicines and Drugs, 2001 edition, recommended that "...an intake of 0.15mg is a safe level for infants (under 3 months) and about 0.5mg up to 2 years.". In response to a request for further information the BMA have indicated that this statement was based on a paper by Phipps *et al.*(2000), which reported that bone fracture risk was not increased in women at levels of fluoride exposure via fluoridated water between 0.025 - 0.11mg/kg b.w. /day. Phipps *et al.* noted that adults in the fluoridated areas they studied had an estimated fluoride intake of between 1.58 and 6.60mg fluoride per day. This would correspond to a potential exposure level of between 0.025 and 0.11mg/kg b.w./day in a 60 kg adult. The fluoride intake level of 0.15mg/day as a safe limit for infants appears to have been derived by taking the lower value of 0.025mg/kg b.w. in the exposure range and applying it to a 3 month old child weighing an average of 6 kg. While this paper supports the evidence that exposure to fluoridated water does not have adverse effects on bone, and does therefore suggest that 0.15mg/day would indeed be a safe limit in respect to this possible adverse effect, it does not provide a basis for estimating a tolerable upper intake level of fluoride in young infants, in relation to dental fluorosis

Although the daily fluoride intakes predicted for young infants by the exposure modelling in this risk assessment may be compared with the values derived by these three expert groups (the TDI of 0.1 mg/kg b.w./day determined by the United States Institute of Medicine, the level of 0.22mg/kg b.w./day of the United Kingdom Department of Health and the intake of 0.15mg total intake per day cited by the BMA), the Scientific Committee concluded that none of the three estimates was totally appropriate as a tolerable upper intake level of fluoride for the group of very young infants in question, in relation to dental fluorosis. It is considered that the threshold fluoride level arrived at by the United States Institute of Medicine is the value best founded in science. However, the question is whether it should be applied to very young infants. The clinical studies carried out by Dean, which are the basis for the USIM threshold value, involved the examination of children from 9 to 14 years

of age. Such children were exposed to fluoride in tap water throughout the 9-14 year period. In his original work Dean noted that dental fluorosis in a 12 year old child merely pointed a presumptive finger to a fluoride ingestion that occurred approximately 8-11 years earlier (Dean 1942). In doing so he was reflecting the view that a critical stage in the formation of the permanent teeth and the fluoride concentration of the blood plasma must coincide before dental fluorosis can develop. This may not be the case in infants less than four months of age since the formation of the enamel of the permanent teeth largely occurs after this period. Therefore, it may not be appropriate to apply the derived threshold value to very young infants unless there is evidence linking early ingestion of fluoride with later development of moderate fluorosis of the permanent dentition. The evidence relating fluoride intake in infancy to moderate dental fluorosis of primary and permanent teeth has therefore been examined in some detail in the hazard characterisation section of this report and is reviewed in the following paragraphs.

Consideration of the evidence for an effect of early fluoride ingestion on the development of moderate fluorosis of the permanent dentition

It has been suggested that elevated intakes of fluoride in early infancy may be a contributory factor in the development of fluorosis in permanent teeth (Foman and Ekstrand, 1993, 1999, Warren *et al.*, 1999, 2001, Fomon *et al.*, 2000) and some studies have reported that the prevalence of fluorosis of the permanent teeth was lower in children who as infants had been breastfed in the first months of life than in those who had been fed on infant formula reconstituted with water containing fluoride (Forsman, 1977; Walton & Messer, 1981; Pendrys *et al.*, 1994). However, it is not clear whether these observations are specifically related to fluoride intake in early infancy or are confounded by intakes at later stages, since, based on the chronology of dental development, it is widely accepted that the period over which the permanent teeth are most susceptible to the development of dental fluorosis lies, not in infancy, but between 15 and 24 months of age for boys and 21 and 30 months for girls (Evans and Darvell, 1995).

It is recognised that early exposure to fluoride from formula feed reconstituted with fluoridated water leads to positive fluoride balance in infants (Ekstrand *et al.*, 1984). In a study of fluoride balance in two groups of infants, one group of which was breastfed and the other group fed a formula diluted with the public drinking water which contained fluoride at a concentration of 1ppm, the authors reported that the daily excretions of fluoride (urinary and faecal) were 31.7mg for the breastfed group and 383mg for the formula fed group. Hence, the breastfed group was undergoing a net loss of fluoride each day (21.1µg per day) while the formula fed group were in strongly positive balance (478µg per day). This may suggest that early exposure to fluoride leads to higher bodily fluoride levels that continue past the first four month period and into the period when some formation of the permanent teeth is starting. However, as yet there is no firm evidence in the literature to support this hypothesis.

If fluoride intake in the first few months of life were to affect fluorosis of the permanent dentition it is reasonable to assume that susceptible infants would first display fluorosis of the primary dentition. In four month old infants the fluoride intake they receive from infant formula reconstituted with fluoridated water is most likely to influence the development of the posterior primary dentition. Diagnosis of fluorosis in primary dentition is difficult and requires careful training of the examiner (O'Mullane Pers. Com.). No studies have been carried out to date in Ireland to quantify fluorosis of the primary dentition.

A number of studies carried out in countries such as Africa with regions of very high natural levels of fluoride in water (3.5-21 mg/l) have reported that fluorosis of primary teeth can be prevalent and severe and probably results from both pre- and post-natal intake of fluoride (Thylstrup, 1978; Olsson, 1979; Mann *et al.*, 1990; Warren *et al.*, 1999). However, studies in Europe and the USA, where fluoride concentrations in water are generally below 2 mg/l show that, although fluorosis of a mild nature occurs with varying prevalence in primary teeth, anterior teeth are rarely affected, and the prevalence of moderate fluorosis in primary teeth is very low (Warren *et al.*, 2001; Forsman, 1977; Booth, 1992; Weeks, 1993; Larsen, 1988). The lower prevalence of fluorosis in anterior primary teeth may be due, at least in part, to the fact that crown development in these teeth is substantially complete at birth.

Forsman (1977) reported that the prevalence of moderate fluorosis of primary teeth (molars) was 4% in children who had resided from birth in a region in Sweden with water fluoride concentration of 2.75 mg/l, but no moderate fluorosis in primary molars was observed in children who had resided from birth in a region with water fluoride concentrations of <0.2, 0.8, 1.5 mg/l. Similarly, no moderate fluorosis was observed in primary teeth in children in regions of Greenland and Denmark with water fluoride levels of 1.1-1.6 mg/l (Larsen *et al.*, 1988) or in the UK with water fluoride levels of 1 mg/l (Booth *et al.*, 1992; Weeks *et al.*, 1993).

Warren *et al.* (2001) reported on the prevalence of fluorosis in primary teeth in 637 children aged 4.5-5 years in the Iowa Fluoride Study cohort residing from birth in regions with water fluoride levels of <0.01 to 2.4 mg/l. This cohort included children who had been exclusively breastfed, exclusively bottle fed and children fed on a mixed bottle/breast feeding regime in early infancy, and 25% had been given fluoride supplements during the first year of life. The prevalence of fluorosis of primary teeth was 11.6% overall (74 children), mainly in first and second molars, with <1% prevalence in anterior teeth (canines and incisors). While the prevalence of fluorosis increased with increasing water concentration, in all but two cases the fluorosis was of a mild nature and not of aesthetic concern.

In conclusion, it is considered that at this point in time there is insufficient evidence to link fluoride intake in the first four months of life to moderate fluorosis of the permanent dentition, although recent studies have shown an effect on the primary dentition. However, the studies reported from other European countries and the USA show that there is very little risk of moderate fluorosis in primary teeth, particularly the anterior teeth, at the levels of fluoride intake estimated for infants consuming infant formula reconstituted in fluoridated tap water in Ireland.

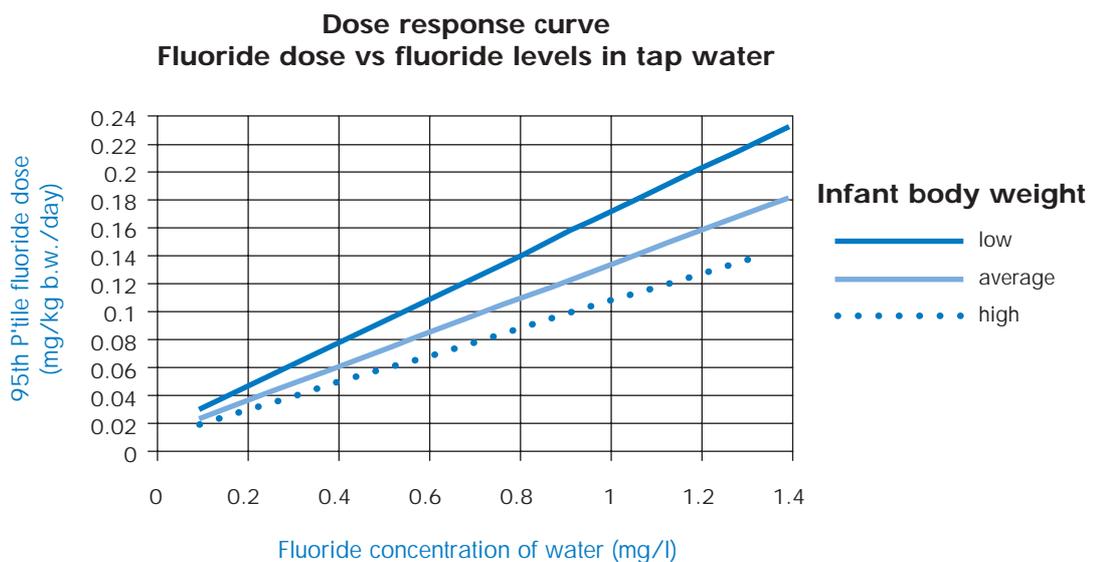
Additional Information for Risk Managers

The exposure assessments in this report relate to exclusively formula-fed infants residing in areas served by the 95% of supplies in which fluoride levels do not exceed statutory limits, based on water fluoridation results from Irish local authorities in 1999. It is clear from the models that the level of fluoride in the water is the single most important factor in determining the fluoride intake ingested by infants. The fluoride concentration results submitted to the EPA demonstrate that in Ireland the administration of fluoride to the water supply is quite variable even though the statutory target range is between 0.8 and 1.0 mg/l. Variation in day to day fluoride concentrations in tap water is not in itself an issue, providing that any high values are below acute toxic levels. However it is the average fluoride concentrations in tap water that are important. In line with the precautionary approach specified above the following options may be of interest to risk managers.

Infants residing in areas served by the 5% of water areas which have greater than the statutory fluoride levels (>1mg/l) are further exposed above the dosage rate calculated in the exposure assessments. A reduction in risk should be achieved by ensuring that all local authorities maintain average fluoride levels in drinking water below the upper bound of the statutory requirement.

A further risk reduction could be achieved by reducing the statutory limit for fluoride in Irish tap water. Using the chronic exposure model it has been possible to examine the relationship between the average fluoride content of tap water and the average daily intake of fluoride of an infant. Figure 14 shows this relationship and may be used by risk managers as an aid in the application of the recommended precautionary approach.

Figure 14: Intake curve for fluoride dose vs. average fluoride concentration in tap water



Conclusions

The following conclusions can be drawn about the possible risks to young infants from the consumption of infant formula reconstituted with fluoridated tap water at current levels of fluoride addition in Ireland.

1. There is no significant evidence that any adverse effect other than dental fluorosis is relevant to a risk assessment of fluoride intake at levels within the range estimated for young infants.
2. The risk of moderate dental fluorosis of the primary or permanent dentition is very low in exclusively formula-fed infants aged 0 to 4 months residing in areas served by the 95% of supplies in which the level of fluoride in water does not exceed the statutory limit. For the remaining infants residing in areas served by the 5% of supplies that consistently exceed the statutory limit, the risk is also considered to be very low, but the safety margin is reduced.

In the absence of data on the prevalence of dental fluorosis in primary teeth in children in Ireland, the Committee recommends the following precautionary measures:

1. All tap water supplies in Ireland should be brought into compliance with the statutory fluoride limits for drinking water.
2. The statutory limit for fluoride in tap water should be examined with the aim of reducing it to the lowest level necessary to achieve the desired level of protection against dental caries.
3. The intake of fluoride in infants and the prevalence of dental fluorosis in infants and children should be monitored on an ongoing basis.

The Committee also reiterates the advice of the FSAI that:

'all babies should be breastfed, except in very rare cases when breastfeeding is medically contraindicated; exclusive breastfeeding should be practised during the first four to six months of life'

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Appendix 1: Toxicological findings in animals and other toxicological studies³

Acute toxicity

Inorganic fluoride is acutely toxic in experimental studies. Reported oral LD 50s (the dose that has lethal effects in 50% of a group of animals studied) in rodents generally lie in the range 50 - 60 mg/kg (for fluoride ion), with values as low as 25 mg/kg and as high as 100 mg/kg being reported. Death follows disturbances in tissue calcium and other electrolyte homeostasis, with cardiac dysrhythmias, hypotension and ultimate failure of the cardiovascular system. The majority of the toxicological data in animals reported in the literature, both acute and chronic, relates to sodium fluoride. Other fluoride salts such as calcium fluoride and hydrofluorosilicic acid (H_2SiF_6 , used commonly in fluoridation of water) are less acutely toxic than sodium fluoride, due to their lower solubility and hence reduced bioavailability in the gastrointestinal tract (Whitford, 1996). The toxicity of sodium monofluorophosphate ($\text{Na}_2\text{PO}_3\text{F}$, MPX, commonly used in dentifrices) is reported to be in the same range as sodium fluoride. Many studies have demonstrated that fluoride is a potent inhibitor of enzymes in biological systems. The dose levels producing inhibition are however reported to be in the millimolar range (Kirk, 1991), whereas plasma and soft tissue fluoride levels following absorption are in the micromolar range (Ekstrand, 1978).

Repeated dose toxicity

Chronic toxicity studies in mice

Mice were exposed to sodium fluoride in their drinking water daily for two years in concentrations of 0, 25, 100 or 175 mg/l (US National Toxicology Programme, NTP 1990). These concentrations were equal to average dose levels of 0, 1.27, 5.11 and 8.50 mg F^- /kg b.w./d for the females and to 0, 1.08, 4.34 and 7.55 mg F^- /kg b.w./d for the males. The diet contained 8.66 mg F^- /kg (equivalent to 1.23 mg/kg b.w./d). Observations included clinical status, body and organ weights (liver, kidneys and brain at interim sacrifices), urinalysis, haematology, clinical chemistry (limited), and complete histopathology. Teeth showed dose-related discolouration and mottling in all groups including the controls, but at higher incidences and earlier in time in the exposed groups. Dental attrition was enhanced in the 175 mg/l dose groups; in the males slightly more pronounced than in the females. Dentine dysplasia was significantly increased in the 175 mg/l males group. Other non-neoplastic lesions were not found. Some neoplastic lesions (lymphomas, hepatocellular neoplasms, Harderian gland adenomas, pituitary adenomas) were seen, but these lesions were either not treatment-related or of no biological significance (NTP 1990) (see also section on carcinogenicity).

³ The risk assessment of Hydrogen Fluoride carried out by the Dutch Ministry of Housing, Spatial Planning and the Environment (VROM) in consultation with the Dutch Ministry of Social Affairs and Employment (SZW) and the Dutch Ministry of Public Health, Welfare and Sport (VWS) is acknowledged as a major source of the toxicological information on fluoride provided in this Annex. The scientific work in this risk assessment was prepared by the Netherlands Organisation for Applied Scientific Research (TNO) and the National Institute of Public Health and the Environment (RIVM), and the full risk assessment report is publicly available on the website of the European Chemicals Bureau, Joint Research Centre, Ispra, Italy. <http://ecb.jrc.it/existing-chemicals/>

In a combined toxicity/carcinogenicity diet study, Maurer *et al.* (1993) exposed mice for two years to nominally 0, 4.0, 10, and 25 mg NaF/kg b.w./d (equal to 0, 1.79, 4.43 and 11.17 mg F⁻/kg b.w./d, respectively). Controls (0 mg/kg b.w./d) received 0.45 mg F⁻/kg b.w./day through the control (low-fluoride) diet. Observations included clinical status, body and organ weights (extensive) and histopathology (extensive). Dose-related changes in teeth were found at 4 mg/kg b.w. and above, comprising fractures, attrition and discolouration, which were accompanied by ameloblast dysplasia, cystic hyperplasia, degeneration and vacuolation. Various skeletal malformations (enostosis, osteosclerosis, hyperostosis) were observed at 10 mg/kg b.w./d and above. Ossification or mineralisation of stifle joints, occasionally together with arthritis were seen in males and females at 10 and 25 mg/kg b.w./day. Soft tissue lesions were not reported. The dental and bone lesions were considered to be related to exposure to fluoride. Other changes in relative organ weights or tissues (including testes) were not found, but quantitative data were not provided. An enhanced number of benign osteomas were observed in which a high density of retroviral particles were seen, especially in the high dose group. The authors concluded that the study was inconclusive with respect to the occurrence of the osteomas, because the presence of the retroviral infection might have enhanced the genesis of these tumours (Maurer *et al.*, 1993) (see also section on carcinogenicity).

Chronic toxicity studies in rats

Rats were exposed to sodium fluoride in their drinking water daily for two years at concentrations of 0, 25, 100 or 175 mg/l (NTP 1990). These concentrations were equal to average dose levels of 0, 0.59, 2.48, 4.29 mg F⁻/kg b.w./d for the females and to 0, 0.50, 2.35 and 3.89 mg F⁻/kg b.w./d for the males. The diet contained 8.66 mg F⁻/kg (equivalent to 0.43 mg/kg b.w./d). Observations included clinical status, body and organ weights (liver, kidneys and brain at interim sacrifices), urinalysis, haematology, clinical chemistry (limited), and complete histopathology. Teeth showed whitish discolouration and mottling with increasing incidences from 25 mg/l, i.e. a No-Effect-Level was not established for this effect. At 100 mg/l and higher these colour changes were accompanied by dental attrition, deformities and malocclusion. In males at 25 mg/l and higher and in females at 100 mg/l and above increases in dentine dysplasia and ameloblast and odontoblast degeneration were found. The effects were more pronounced in male animals. In the females of the 175 mg/l group an increased incidence in osteosclerosis was observed. In male animals osteosarcomas were observed with incidences of 0/80, 0/51 1/50 and 3/80 in the 0, 25, 100 and 175 mg/l groups, respectively. Osteosarcomas were not reported for the females. The authors considered the results equivocal with respect to the carcinogenic potential of sodium fluoride. No other indications for the formation of neoplastic lesions were obtained; nor were other treatment-related lesions found (NTP 1990) (see also section on carcinogenicity).

In a combined toxicity/carcinogenicity study, Maurer *et al.*, (1990) exposed rats for two years to 0, 4.0, 10, and 25 mg NaF/kg b.w./day (equal to 0, 1.81, 4.52 and 11.24 mg F⁻/kg b.w./d, respectively). Controls (0 mg/kg b.w./d) received 0.16 mg F⁻/kg b.w./day through the control (low-fluoride) diet. Observations included clinical status, body and organ weights (extensive) and histopathology (extensive), clinical chemistry (not specified), and urinalysis (not specified). Dental aberrations (ameloblast dysplasia and enamel hypoplasia) were dose-

relatedly increased in all treatment groups, i.e. a No-Effect-Level was not established for this effect. Dental fractures and malocclusions were enhanced at 10 and 25 mg/kg b.w./day. Males and females were equally sensitive to the reported effects. Subperiosteal hyperostosis was observed in particular in the bones of the skulls of males at 10 mg/kg b.w./d and above. In the females this effect was less pronounced. Relative and absolute stomach weight was significantly increased at 10 mg/kg b.w./d and above. Mononuclear cell infiltration of the glandular epithelium was dose-relatedly increased from 4 mg/kg b.w./d in the male and from 10 mg/kg in the females. Chronic inflammation and regeneration of the glandular mucosa occurred in the males at 10 mg/kg and above. In the females these effects were seen at 4 mg/kg and above and at 25 mg/kg b.w. respectively. No treatment-related effects were reported in 24 other tissues (including testes), but quantitative data were not provided. In some animals neoplastic bone lesions were seen (sarcoma, osteosarcoma, chordoma, chondroma) but these lesions were incidental and randomly distributed among the groups. In the stomach of one control male a papilloma was found. Other soft tissue neoplasms were not reported in detail but it was stated that "there was no evidence that fluoride altered the incidence of preneoplastic and neoplastic lesions at sites of fluoride toxicity or at any other site in rats of either sex" (Maurer *et al.*, 1990) (see also section on carcinogenicity).

Dunipace *et al.*, (1998a) carried out a series of studies on the effects of fluoride administered chronically to nutritionally deficient rats. In a study designed to examine the effects of administration of 0, 5, 15 or 50 mg/L fluoride in drinking water (average dose levels of 0, 0.12, 0.36 or 1.24 mg F⁻/kg b.w./day for the females and to 0, 0.10, 0.30 or 1.18 mg F⁻/kg b.w./day for the males) for 16 or 48 weeks to rats receiving a calcium deficient diet, levels of plasma and tissue fluoride increased as dietary calcium was decreased (from 0.5% to 0.25 % or 0.125%), associated with decreased faecal excretion and increased g.i. absorption of fluoride. Although the level of dietary calcium had a primary effect on animal growth/bodyweight gain and on clinical chemistry, blood or urine parameters, increasing levels of fluoride administered via drinking water had no further effects on these parameters despite the markedly increased levels of tissue fluoride detected in the animals. In a second study, the effects of administration of 0, 5, 15 or 50 mg/L fluoride in drinking water for 16 or 48 weeks to rats receiving a protein-deficient diet provided similar results. The authors concluded that there were no harmful extraskkeletal, biochemical or physiological effects of fluoride at levels up to 50 mg/L in drinking water in nutritionally-deficient animals.

The same authors (Dunipace *et al.*, (1998b) carried out a similar study on the effects of fluoride administered chronically to renally-compromised rats. Rats were made uremic by partial nephrectomy and were then administered 0, 5, 15 or 50 mg/L fluoride in drinking water for 16 or 48 weeks. Although the uremic state resulted in effects on animal growth/bodyweight gain and on clinical chemistry, blood or urine parameters, increasing levels of fluoride administered via drinking water had in general no further effects on these parameters, although animal growth was further depressed in the group of animals receiving 50 mg/L. This lack of effect was despite the markedly increased levels of tissue fluoride detected in the nephrectomised animals, due to impaired renal clearance.

Carcinogenicity studies in rats and mice

Four studies with sodium fluoride have been performed, as already outlined under Repeated Dose Toxicity above. In two of these, sodium fluoride was supplied in the drinking water to rats and mice, and in two it was administered via the diet, again to rats and mice. In the rat drinking water study, equivocal evidence was obtained for induction of osteosarcomas in males, but the rat diet study was negative, despite clear indications of fluoride intoxication. The mouse drinking water study was also negative. The mouse diet study was confounded by the presence of a retrovirus which may have (co)-induced the growth of benign osteomas, thus thwarting the interpretation of the study. In the diet studies (Maurer *et al.*, 1990; Maurer *et al.*, 1993) bone fluoride levels were higher than in the drinking water studies (NTP 1990), but despite the higher body burden of fluoride no osteosarcomas were seen. Furthermore, the osteomas seen in the mouse diet study were considered to be reminiscent of hyperplasias rather than true bone neoplasms. The animal carcinogenicity data have been considered by many expert groups, and the overall conclusion has been that fluoride is not a carcinogenic substance in animals (Janssen, and Knaap 1994) (see also discussion under carcinogenicity in humans).

Toxicity for reproduction

The 1993 publication from the National Research Council 'Health Effects of Ingested Fluoride' noted that there were many studies in a whole variety of animal species showing reproductive effects of fluoride, but generally only with exposures in the diet or water of 100-200 parts per million (ppm) or more, where effects such as thinning of eggshells were observed (Whitford, 2001, personal communication).

Several animal studies have indicated that oral exposure to fluoride may damage testicular tissue and potentially reduce male fertility. Chinoy and Sequeira (1989, 1992) carried out two fertility studies in the mouse, with oral exposure to 0, 10, 20 mg NaF/kg b.w. daily for 30 days, and demonstrated reversible histological changes in testis, epididymis and vas deferens, reversible decreased sperm motility and sperm count and infertility and abnormal sperm morphology, with a Lowest Observable Adverse Effect Level (LOAEL) of 10 mg NaF/kg b.w. (~4.52 mg F⁻/kg b.w.). The same authors (Chinoy *et al.*, 1991) reported reduction of fertility, decreased sperm counts and motility, biochemical changes in testes, epididymis and prostate in rats administered 0, 5 and 10 mg NaF/kg b.w. daily for 30 days. The LOAEL for these effects was 2.26 mg F⁻/kg b.w./day.

However, in a recently completed and well-conducted multigeneration study by the US Food and Drug Administration (FDA) (Collins *et al.*, 2001) no testicular effects were seen at an exposure level of 250 mg NaF/l (equivalent to about 10 mg F⁻/kg b.w./d). Numbers of corpora lutea, implants, viable fetuses and fetal morphological development were similar in all groups. This latter study can be considered to provide a NOAEL for effects on fertility. Ossification of the hyoid bone of F2 fetuses was significantly decreases at 250 ppm. In the available animal studies on embryo- and developmental toxicity, some embryotoxicity was observed. The results of three US FDA studies with sodium fluoride provide a NOAEL of 11.12 mg F⁻/kg b.w./d for maternal toxicity and developmental effects.

In relation to developmental toxicity there are a number of studies in the literature that show no fluoride-related effect on foetal development. These include the study of Collins *et al.*, (1995), who investigated the oral developmental toxicity of sodium fluoride in rats, administered via the drinking water (ultra pure) in concentrations of 0, 10, 25, 100, 175 and 250 mg NaF/l, daily throughout gestation. Groups of 33 to 37 females were mated with untreated males. Actual dose levels were 0, 0.63, 1.76, 7.06, 11.12 and 11.35 mg F⁻/kg b.w. All animals received a low fluoride diet containing 7.95 mg F⁻/kg feed which resulted in an additional exposure to approximately 0.6 F⁻ mg/kg b.w./day. The observations included maternal toxicity (behavioural and clinical signs including dental mottling, feed and drinking water intake, body weight) and toxicity in the off-spring (numbers of live and dead foetuses, implantations, resorptions, numbers of corpora lutea, sex, weight, external examination, skeletal abnormalities and soft tissue aberrations).

Clinical signs of toxicity in the dams were not seen, but at the highest two dose levels drinking water consumption and at the highest dose level feed intake were diminished. At 250 mg/l dams showed reduced growth. At the highest level of exposure, a slight reduction in corpora lutea and number of implants per dam was seen, but these observations were not considered to be linked to the exposure of the dams to fluoride. No signs of retarded foetal development were obtained. At the highest dose level a limited but statistically significant increase in the number of foetuses with skeletal variations was found. The number of litters affected was not significantly increased. Thus this study did not reveal relevant reproductive or developmental toxicity resulting from fluoride at dose levels up to 250 mg/l. At this level maternal toxicity was observed. The NOAEL for maternal toxicity and developmental effects in this study was 11.12 mg F⁻/kg b.w./day (Collins *et al.*, 1995).

In another study by the US National Toxicology Programme (NTP) (Heindel *et al.*, 1996), sodium fluoride was administered via the drinking water to rabbits and rats. Groups of 26 female rats received 0 (\leq 0.6), 50, 150 or 300 mg NaF/l in deionised water from day 6 through day 15 of gestation. The feed contained about 12.4 mg/kg fluoride (average value). Actual intake of fluoride via the drinking water amounted to \approx 0.3, 3.0, 8.4 and 12.3 mg F⁻/kg b.w./day. Fluoride in feed resulted in an additional exposure of 1.0 mg F⁻/kg b.w./day. With the highest dose administered the authors aimed at the induction of some maternal toxicity while avoiding dehydration effects due to reduced water intake resulting from the lack of palatability of sodium fluoride solutions. Observations included maternal toxicity (clinical signs, weight gain, water and feed consumption, liver and kidney weights) and toxicity in the offspring (number of litters, corpora lutea, implantation sites, resorptions, late death, live foetuses, foetal body weights, sex ratio, external and skeletal and soft tissue malformations). The only significant effect on the dams was a reduced water intake in the high dose group during the treatment. No indications for embryo-, foeto- or developmental toxicity were obtained. The NOAEL in this study for developmental of foetotoxicity was therefore equal to the highest level tested, namely 12.3 mg/kg b.w./d (Heindel *et al.*, 1996).

In the same study report (Heindel *et al.*, 1996), the results of exposure of groups of 26 rabbits to 0 (\leq 0.6), 100, 200 and 400 mg NaF/l in the drinking water for day 6 through 19 of gestation have been described. Exposure via the drinking water amounted to \leq 0.1, 4.7,

8.2 and 13.2 mg F⁻/kg b.w./d, whereas exposure via food contributed about 0.8 mg F⁻/kg b.w./d to the total fluoride intake. As with the rats observations included maternal toxicity (clinical signs, weight gain, water and feed consumption, liver and kidney weights) and toxicity in the offspring (number of litters, corpora lutea, implantation sites, resorptions, late death, live foetuses, foetal body weights, sex ratio, external and skeletal and soft tissue malformations). Dams exposed to the highest fluoride level demonstrated reduced water intake during the exposure period and a reduced feed intake on days 6 through 8 of gestation resulting in a reversible loss of body weight over these days. No (other) signs of maternal toxicity were obtained. Examination of uteri and offspring did not reveal any sign of embryo-, foeto- or developmental toxicity. The NOAEL for reproductive effects in this study was therefore 13.2 mg/kg b.w./day (highest level tested).

Genotoxicity

Test results show that hydrofluoric acid (HF) and sodium fluoride (NaF) are both negative for genotoxic effects in bacterial test systems (Bayer AG 1987, NTP 1990). In eukaryotic systems *in vitro* NaF induces Sister Chromatid Exchange (SCE), Unscheduled DNA Synthesis (UDS) and chromosomal aberrations at levels of 4.5 mg F⁻/l and above (NTP 1990; Tsutsui *et al.*, 1984a, b; Aardema *et al.*, 1989, Aardema and Tsutsui, 1995, Khalil 1995). A well-performed *in vivo* assay with NaF showed that fluoride did not cause chromosomal damage in mice (Zeiger *et al.*, (1994). However, positive *in vivo* results were scored in anaphase cells, indicating a possible indirect effect. Since it is unlikely that F⁻ binds to DNA covalently, a prerequisite for DNA-adducts, the DNA damage observed in *in vitro* studies is probably not caused by a direct interaction of fluoride with DNA. It is concluded that inorganic fluoride does not induce chromosomal damage *in vivo*. (VROM, SZW, VWS, 1999). In the studies of Dunipace *et al.* (1998a,b) involving administration of 0, 5, 15 or 50 mg/L fluoride in drinking water (average dose levels of 0, 0.12, 0.36 or 1.24 mg F⁻/kg b.w./d for the females and to 0, 0.10, 0.30 or 1.18 mg F⁻/kg b.w./d for the males) for 16 or 48 weeks to nutritionally-deficient or renally compromised rats, no increase in the frequency of SCE was detected in the bone marrow in the fluoride-treated rats.

The studies described above provide some evidence of a genotoxic potential of fluoride *in vitro*, but only at cytotoxic concentrations with low cell survival. There is no evidence that fluoride is genotoxic in *in vivo* studies.

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