

No. R. 873

8 September 2000

REGULATIONS UNDER THE HEALTH ACT, 1977 (ACT NO. 63 OF 1977)

The Minister of Health has, under section 37, read with section 40(1), of the Health Act, 1977 (Act No. 63 of 1977), and after consultation with the Minister of Water Affairs and Forestry, made the regulations in the Schedule.

SCHEDULE**REGULATIONS ON FLUORIDATING WATER SUPPLIES****Definitions**

1. In these regulations any expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise –

“authorised officer” means an officer of the national Department of Health or of a provincial government or any other person generally or specifically authorised in writing by the Director-General;

“Director-General” means the Director-General of the national Department of Health;

“fluoridation” means to adjust the fluoride concentration of a water supply by the addition of a fluoride compound to obtain an optimal fluoride concentration;

“fluoride compound” means sodium fluoride (NaF), sodium fluorosilicate (Na_2SiF_6) (also known as sodium silicofluoride) or fluorosilicic acid (H_2SiF_6);

“optimum fluoride concentration” means a fluoride concentration of not more than 0,7 milligrams fluoride per litre in a water supply;

“the Act” means the Health Act, 1977 (Act No. 63 of 1977);

“waste water discharges” means water discharges containing waste;

“waste” means any solid material or material that is suspended, dissolved or transported in water (including sediment) and which is spilled or deposited on land or into a water resource in such volume, composition or manner as to cause, or to be reasonably likely to cause, the water resource to be polluted;

“water distribution system” means the supply of water by a water provider through pipes to the end user;

“water fluoridation plant” means the equipment used and the procedures applied in the addition of a fluoride compound to a water supply;

“water fluoridation scheme” means the delivery to the end user of water containing an optimum concentration of fluoride, which is supplied by a water fluoridation plant through a water distribution system;

“water provider” means any drinking-water treatment authority, body or organisation supplying drinking water from its treatment facility;

“water resources” means a watercourse, surface water, estuary or aquifer;

“water supply” means the supply of water intended for human use or food processing.

Obligation

2. Every water provider must practise fluoridation, unless exempted in writing by the Director-General.
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Registration

3. (1) Every water provider practising as such immediately prior to the promulgation of these regulations must, within 12 months after the promulgation of these regulations, submit –
 - (a) an application for registration, in duplicate, in the format set out in Annex A; and
 - (b) a form on technical information set out in Annex C,to the Director-General.
- (2) A water provider commencing operations as such after the promulgation of these regulations must, within 12 months of becoming a water provider, register with the Director-General as contemplated in subregulation (1).
- (3) A water provider must enter into an agreement with the local authority whose population is supplied by such water provider if the water provider is not itself a local authority.
- (4) Information regarding an agreement referred to in subregulation (3) must be indicated by the water provider in paragraph 6 of Annex A when the water provider submits its application for registration, referred to in subregulation (1).

Public information

4. (1) A water provider must, once these regulations have been promulgated or when commencing operations, inform every local authority to whom it supplies drinking water that the water supply will be fluoridated.

- (2) The local authority referred to in subregulation (1) must, once these regulations have been promulgated or when a water provider in such local authority's area commences operations, inform the public concerned by means of a notice in two or more regional newspapers generally read by the public in the area in question regarding the intended fluoridation of their water supply.
- (3) The notice referred to in subregulation (2) must state that interested persons are invited to submit any substantiated comments on the intended fluoridation of their water supply or representations they wish to make in regard thereto to their local authority within 30 days of the date of publication of such notice.
- (4) In addition to the publication of the notice referred to in subregulation (2), the local authority must also broadcast the content of such notice on an appropriate radio station.
- (5) A water provider must attach the comments received by the local authority from the public to the application for registration referred to in regulation 3.

Consideration by Director-General regarding implementation of fluoridation by water provider

5. (1) The following information must be taken into account by the Director-General:
 - (a) Dental caries experience in the supply area of the water provider;
 - (b) the population size in the supply area of the water provider;
 - (c) the estimated per capita costs of fluoridation in the supply area of the water provider;

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- (d) the feasibility of using alternative fluoride supplements; and
 - (e) the information required in Annex A.
- (2) The information referred to in subregulation (1) must, at the written request of the Director-General, be submitted by public oral health services, water providers and local authorities, as applicable.
 - (3) The Director-General must consult with the Director-General of Water Affairs and Forestry regarding any possible influence of the proposed fluoridation of the water resources in the affected areas and; should the Director-General of Water Affairs and Forestry be of the opinion that there may be an unacceptable impact on these water resources, the Director-General may require the water provider to carry out an assessment of this impact.
 - (4) The assessment referred to in subregulation (3) must be evaluated by the Director-General and the Director-General of Water Affairs and Forestry.
 - (5) After a water provider's application for registration has been registered, such water provider must implement fluoridation within a period of not more than two years, or within such extended period as determined by the Director-General upon a written request by the water provider.
 - (6) The Director-General may at any time before or after a water fluoridation plant comes into operation, request a water provider to submit any other additional information on the water fluoridation scheme to him or her.
 - (7) If a water provider makes any changes, except with regard to the optimum fluoride concentration, after the implementation of fluoridation, which differ with regard to any of the items specified as technical information in Annex C, such water provider must inform the Director-General in writing regarding such changes and the reasons therefor.

- (8) The Director-General determines the optimum concentration of fluoride in the water supplied by a water provider.
- (9) If a water provider wishes to amend the optimum fluoride concentration referred to in subregulation (8), as approved by the Director-General, such water provider must apply in writing to the Director-General for approval to amend the optimum fluoride concentration, stating the reasons for such amendment.
- (10) The Director-General may authorise an officer from the national or a provincial Department of Health or any other person authorised by him or her to carry out any prescribed inspection of a water fluoridation plant at any reasonable time, and may request any specified report on the functioning of the water fluoridation scheme to be submitted to him or her.

Exemption of water provider from implementation of fluoridation, or termination of fluoridation

- 6. (1) If a water provider wishes to be exempted from the implementation of fluoridation or wishes to terminate the fluoridation of a water supply, such water provider must submit its application for such exemption or termination in duplicate to the Director-General in the format set out in Annex B.
- (2) The Director-General must use the criteria and guidelines in Annex D to determine whether an application referred to in subregulation (1) should be approved or not.
- (3) If the Director-General is of the opinion that such an exemption or termination is necessary, the Director-General must approve such an exemption or termination.

- (4) The Director-General may withdraw his or her approval referred to in subregulation (3) for a specific period if he or she is of the opinion that such an exemption or termination is unnecessary.
- (5) The Director-General must approve an application for exemption or termination in consultation with the Director-General of Water Affairs and Forestry, if the latter is of the opinion that the water provider concerned should be exempted from the implementation of fluoridation or permitted to terminate the fluoridation of a water supply owing to the unacceptable impact on the water resources receiving fluoridated water or waste water discharges.
- (6) The Director-General must inform the water provider concerned in writing whether its application referred to in subregulation (1) has been approved or not, as well as provide the reasons in the case of disapproval.

Appeals

7. (1) Any local authority, water provider, other authority, public organisation or body may appeal in writing to the Minister against any decision made by the Director-General in terms of any provision of these regulations.
- (2) An appeal in terms of subregulation (1) must be lodged within 60 days of the decision appealed against having come to the knowledge of the local authority, water provider, other authority, public organisation or body, as the case may be, and must clearly state –
 - (a) against which decision such appeal is lodged; and
 - (b) the grounds on which such appeal is lodged.
- (3) An appeal in terms of these regulations must be lodged with the Director-General, who must submit it to the Minister, together with his or her reasons for the decision against which the appeal is being lodged.

- (4) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these regulations and inform the local authority, water provider, other authority, public organisation or body, as the case may be, in writing of his or her decision.

Operational criteria for fluoridation

8. (1) The water fluoridation plant must –
- (a) be of such design as to be capable of ensuring the fluoride concentration indicated under point 3 of Annex C; and
 - (b) incorporate alarm arrangements to prevent the overdosing of a water supply with fluoride resulting in more than 1,0 milligrams fluoride per litre above the optimum fluoride concentration indicated under point 3 of Annex C as a result of a breakdown or malfunction of any part of the water fluoridation plant equipment or a change in the flow rate of the fluoridated water.
- (2) Only a fluoride compound approved by the Director-General in terms of regulation 14 of these regulations shall be used to fluoridate a water supply.
- (3) The fluoride compounds referred to in subregulation (2) must be stored in a secure place by a water provider so that –
- (a) any unforeseen or accidental spillage of such fluoride compound does not contaminate the environment or cause injury; and
 - (b) no unauthorised person can tamper with such fluoride compounds.

- (4) A water provider must ensure that the fluoride concentration in the fluoridated water, measured at a point soon after the addition of the fluoride compound referred to in subregulation (2) and the mixing thereof with the water, is maintained within 0,2 milligrams fluoride per litre of the optimum fluoride concentration indicated under point 3 of Annex C.
- (5) The fluoride concentration referred to in subregulation (4) must be maintained at least 90 percent of the time.
- (6) The average monthly fluoride concentration of the fluoridated water, calculated for the periods when the water fluoridation plant is in operation, must not deviate by more than 0,1 milligrams fluoride per litre from the optimum fluoride concentration indicated under point 3 of Annex C.
- (7) If a water fluoridation plant is shut off for a period of two months or longer, for whatever reasons, the water provider concerned must inform the relevant local authorities who must inform the public concerned by means of a notice in two or more local newspapers and broadcasting on an appropriate radio station.

Monitoring of the fluoride concentration

9. (1) The fluoride concentration of the fluoridated water leaving the water fluoridation plant must be monitored by –
 - (a) a continuous-recording fluoride monitor which is calibrated once every 24 hours; or
 - (b) the sampling of such fluoridated water in every shift, using the analytical procedures laid down by the Department of Health as specified in the Technical Manual for Water Plant Operators.
- (2) The fluoride monitor referred to in subregulation (1)(a) must be linked to an alarm system which should be activated when the fluoride

concentration exceeds 1,7 milligrams fluoride per litre for a period of more than five minutes.

- (3) In the case of sampling referred to in subregulation (1)(b), the water fluoridation plant must be staffed 24 hours per day to ensure proper functioning.
- (4) A minimum of one sample per week must be taken randomly from a number of places in the distribution system and the result recorded.
- (5) The number of samplings referred to in subregulation (4) will depend on the layout of that distribution system.

Record keeping and reporting

10. (1) The water provider must record the following particulars daily for the first month after a water fluoridation plant has come into operation, and thereafter daily or at any other interval not exceeding seven days:
 - (a) The volume of water fluoridated after the last recording;
 - (b) the amount of fluoride used in the water referred to in paragraph (a);
 - (c) the average fluoride concentration of the fluoridated water leaving the plant after the last recording;
 - (d) the average fluoride concentration, based on historical information or on actual measurement, in the unfluoridated water which entered the water fluoridation plant after the last recording;
 - (e) the average monthly fluoride concentration in the fluoridated water leaving the water fluoridation plant, as recorded by the fluoride monitor referred to in regulation 9(1)(a), as well as the highest and
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- lowest fluoride concentration in such fluoridated water during that month;
- (f) the average monthly fluoride concentration in the samples referred to in regulation 9(1)(b), as well as the highest and the lowest fluoride concentration in such samples during that month; and
 - (g) remarks on any events such as breakdowns, equipment failure, repairs, maintenance or any other activity that may have an effect on the fluoride concentration referred to in paragraphs (c), (d), (e) and (f), and whether steps were taken to prevent the recurrence of such events or activities.
- (2) The amount of fluoride referred to in subregulation (1)(b) is determined by the subtraction of the amount of fluoride in stock at the end of the present period from the sum of the amount of fluoride received on site after the last recording and the amount of fluoride in stock at the beginning of the present period.
- (3) The average fluoride concentration referred to in subregulation (1)(c) and (d) is determined by the following factors:
- (a) The volume of the water referred to in subregulation (1)(a);
 - (b) the amount of fluoride added to such water; and
 - (c) the fluoride content of the unfluoridated water referred to in subregulation (1)(d).
- (4) A monthly summary of the records referred to in subregulation (1) must be submitted by a water provider to the health department of the local authority concerned and to other relevant health authorities, together with a report on any non-compliance with subregulation (1), (5), (6) or (7) and the steps taken to prevent a recurrence of such non-compliance.

- (5) The records referred to in subregulation (1) and the report referred to in subregulation (4) must be submitted by the water provider via the local and provincial health authority, to the national Department of Health for audit as deemed necessary by the local or provincial health authority or the national Department of Health.
- (6) Any incident of an overdose of between 1,7 milligrams and 10 milligrams fluoride per litre in a 24-hour period must be recorded and reported immediately to the health department of the local authority concerned and to any other health authority concerned.
- (7) Accidental over-fluoridation of more than 10 milligrams per litre or a major spill must be recorded, and the water provider must inform the local and provincial health authority, the Director-General, the Director-General of Water Affairs and Forestry, as well as the users of such water, immediately or as soon as is practicable.
- (8) All records and reports of a water provider relating to fluoridation must be open for public inspection and must be kept for a period of ten years.
- (9) A summary of the records and reports referred to in subregulations (4), (5) and (6) must be submitted by the water provider to the local authorities concerned, who will in turn submit it to –
 - (a) the MEC for Health of the responsible provincial government, every three months;
 - (b) the Director-General of the national Department of Health, annually; and
 - (c) the Director-General of the Department of Water Affairs and Forestry, annually.

Inspections

11. (1) An authorised officer may at any time, and as often as he or she may deem necessary, inspect a water fluoridation plant.
- (2) The owner or occupier or the person in charge or apparently in charge of, or any employee on or in a water fluoridation plant, must render to the authorised officer in terms of these regulations all information the authorised officer may require with regard to the organisation and management of a water fluoridation plant and the process of fluoridation.
- (3) No person may in any way obstruct an authorised officer in carrying out his or her inspections or refuse to furnish to the best of his or her knowledge any information requested by such an authorised officer.

The operation, maintenance and employees of a water fluoridation plant

12. (1) A water provider must establish a comprehensive operational programme, safety measures and emergency procedures regarding -
- (a) the operation of the water fluoridation plant;
 - (b) the inspection, servicing and maintenance of the equipment of the water fluoridation plant;
 - (c) the monitoring of the fluoride concentration referred to in regulation 9; and
 - (d) the storage and handling of fluoride compounds at the water fluoridation plant,

in order to achieve consistent, effective and safe performance of the water fluoridation plant.

- (2) The operational programme, safety measures and emergency procedures referred to in subregulation (1) must be made available in written format to the managers, supervisors, operators, maintenance staff and other employees working at the water fluoridation plant in accordance with their duties, responsibilities and tasks.
- (3) A water provider must ensure that the people referred to in subregulation (2) are adequately trained in all aspects of their duties, responsibilities and tasks.
- (4) The operator of a water fluoridation plant must have a classification of at least Class III, in accordance with the classification system for water-care plant operators of the Department of Water Affairs and Forestry.

Health and safety

13. All activities related to a water fluoridation plant must be in compliance with the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

Fluoride compounds

14. (1) The following fluoride compounds may be used in the fluoridation of a water supply:
 - (a) Sodium fluoride;
 - (b) fluorosilicic acid;
 - (c) sodium fluorosilicate.
- (2) Potential importers or manufacturers must apply to the Director-General for registration and approval of fluoride compounds other than those mentioned in subregulation (1) prior to the fluoridation of a public water supply.

- (3) A water provider must ensure that the compounds used meet the quality standards of the Department of Health as described in the Technical Manual for Water Plant Operators, published by the Department of Health.
- (4) Documentary evidence of the quality of the fluoride compound to be used must be submitted to the Department of Health by the water provider concerned.

ANNEX A**APPLICATION BY A WATER PROVIDER FOR REGISTRATION
TO FLUORIDATE A WATER SUPPLY**

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|--|---------------|
| 1. Name and address of water provider: | |
| Name of responsible person: | Telephone no: |
| | Cellular no: |
| | Fax no: |
| Position/rank: | |
| Name of responsible person from the appropriate health authority: | Telephone no: |
| | Cellular no: |
| | Fax no: |
| Position/rank: | |
| 2. Volume of water supplied per month: | |
| 3. List separately the names of local authorities supplied with drinking water by the water provider and the number of people in the supply area(s). | |

4. The following information may also be provided separately if more space is required:

(a) Source(s) of raw water [i.e. point(s) of abstraction]

- * River catchment(s)
- * River(s)/Dam(s)/Other
- * Location(s) of drinking water treatment facility/facilities

(b) Point(s) of discharge of effluent(s) originating from the proposed fluoridated water supply/supplies in the supply area covered by the water provider

- * River catchment(s)
- * River(s)/Dam(s)/Other
- * Location(s) of effluent treatment facility/facilities

5. Attach comments received from the public [regulation 4(5)]

6. Provide information on the agreement reached between the water provider and the local authority with respect to :

- (a) The terms of the agreement between the water provider and the local authority;
- (b) the respective responsibilities for ongoing monitoring and reporting on fluoride levels in the water supply; and
- (c) action to be taken in the event of over-fluoridation [regulation 10(7)]

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| Signature: |
| Name: |
| Position/Rank: |
| On behalf of: |
| Date: |

For office use only:

Registration number:

Registration date:

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For Director-General
Department of Health

Date:

ANNEX B**APPLICATION BY A WATER PROVIDER TO BE EXEMPTED FROM THE
IMPLEMENTATION OF FLUORIDATION OR TO TERMINATE THE FLUORIDATION
OF A WATER SUPPLY**

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| 1. Name and address of water provider: | |
| Name of responsible person: | Telephone no: |
| | Cellular no: |
| | Fax no: |
| Position/rank: | |
| Name of responsible person from the appropriate health authority | Telephone no: |
| | Cellular no: |
| | Fax no: |
| Position/rank: | |
| 2. Place where water fluoridation plant is installed: (in the case of termination only) | |

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| 3. Reason(s) for requesting exemption from the implementation of fluoridation or for the termination of fluoridation of a water supply: |
| Signature: |
| Name: |
| Position/Rank: |
| On behalf of: |
| Date: |

For office use only:

Approved/Not approved

.....
Director-General
Department of Health

Date:

ANNEX C**TECHNICAL INFORMATION PROVIDED BY THE WATER PROVIDER**

Technical information to be submitted by the water provider to the Director-General.

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| 1. Name and address of water provider: | |
| Name of responsible person: | Telephone no: |
| | Cellular no: |
| Position/rank: | Fax no: |
| Name of responsible person from the appropriate health authority: | Telephone no: |
| | Cellular no: |
| Position/rank: | Fax no: |
| 2. Place where water fluoridation plant is installed: | |
| 3. (a) Amount of water to be fluoridated per month: | |
| (b) Fluoride compound to be used: | |
| (c) Mean annual fluoride concentration of present water supply: | ...mg F/l |
| (d) Proposed optimum fluoride concentration (not more than 0,7 mg F/l): | ...mg F/l |
| 4. Name and description of areas to be supplied with fluoridated water: | |

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| <p>5. Explanatory documentation attached:</p> <p>(a) Steps taken to inform the public.</p> <p>(b) Types and names of fluoridation monitoring equipment and description of fluoride monitoring and alarm systems.</p> <p>(c) Fluoridation plant inspection, servicing and maintenance programme, and emergency procedures.</p> <p>(d) Employee training programme and duty sheets.</p> <p>(e) Agreement between local authority and water provider, if applicable.</p> |
| Signature: |
| Name: |
| Position/Rank: |
| On behalf of: |
| Date: |

For office use only:

Registration number:

Registration date:

.....
For Director-General
Department of Health

Date:

ANNEX D

Criteria and guidelines for the exemption of a water provider from the implementation of fluoridation or for the termination of fluoridation

Introduction

On a submission of an application and under specific circumstances the Director-General may allow the exemption of a water provider from the implementation of fluoridation or for the termination of fluoridation of a water supply. This document defines the nature of the circumstances under which such an exemption or termination should be granted. It focuses on the criteria that should be used in determining the outcome of an application for exemption or termination. Such an application by the water provider must be submitted in the format provided for in Annex B.

Criteria

The following three elements are necessary for successful fluoridation:

- (a) The water;
- (b) the community; and
- (c) specific resources.

Difficulties with any one of these elements can make the implementation of a fluoridation programme impossible for a period of time. Taking these three elements into consideration, the Director-General should specify the period for which exemption from the implementation of fluoridation is granted.

These elements are examined separately to determine the criteria that would make fluoridation either impossible or unnecessary, which would then mean that alternative methods of fluoride supplementation should be considered.

- (a) The water - If the raw water available to a supplier already contains the optimum concentration of fluoride as defined in the regulations, or more, then fluoridation is unnecessary and should not be undertaken.
- If the raw water available to a supplier is available intermittently only, then reliable fluoridation can be problematic and should not be undertaken.
 - If it is demonstrated that fluoridation of a water supply will have unacceptable impacts on those water resources which receive effluent or diffuse discharges originating from the fluoridated supplies, exemption or termination should be approved.
- (b) The community - A community may have limited experience of dental decay and therefore, so long as this remains the case, there is no need for fluoridation.
- (c) Specific resources -
- Staff - Properly trained staff are vital to the success of fluoridation. Until such staff are appointed, temporary exemption from the implementation of fluoridation should be granted.
 - Equipment - Fluoridation requires accurate and well maintained equipment. Until such equipment is available, temporary exemption from the implementation of fluoridation should be granted.
 - Chemicals - Specific chemicals in appropriate quantities are needed on a continuing basis for successful fluoridation. Until such chemicals are available, temporary exemption from the implementation of fluoridation should be granted.

