



guardians of drinking water quality

Guidance on the Water Supply (Water Quality) Regulations 2000^a specific to N-nitrosodimethylamine (NDMA) concentrations in drinking water

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^a 2001 in Wales

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Summary

N-nitrosodimethylamine (NDMA) is a by-product of industrial processes that use nitrate and/or nitrite and amines. It can also be formed during sewage treatment and during water treatment as a disinfection by-product. It is generally accepted as being a genotoxic carcinogen.

Recent research commissioned by DWI on behalf of Defra assessed the occurrence of NDMA in drinking water in England and Wales (available at www.dwi.gov.uk/research). Overall the research findings are reassuring. At over 90% of the treatment works, samples of final water were free from detectable concentrations of NDMA (limit of detection 0.9ng/l). At three treatment works, trace levels of NDMA were found in the final water, all final water concentrations were below 10 ng/l, as compared to the proposed WHO guideline value of 100ng/l.

Although the Inspectorate is not aware of NDMA being found at concentrations which would cause concern in drinking water in England or Wales, given that concentrations have been detected in a small number of treated waters and Health Protection Agency (HPA) advice is that this compound should be regarded as a genotoxic carcinogen, the Inspectorate considers it appropriate to provide specific guidance to water companies.

This document is based on a multi-tiered approach to the protection of water safety. It provides guidance on the concentrations of NDMA that water companies should act upon in order to fulfil their statutory obligations to ensure the safety of drinking water. The guidance values are summarised in the table below:

Item	Regulatory requirement	Trigger	Minimum action to be taken
N-nitrosodimethylamine (NDMA)			
Tier 1	Regulation 27 (Risk assessment)	potential hazard	<ul style="list-style-type: none"> Ensure considered as part of statutory risk assessment
Tier 2	Regulation 10 (Sampling: further provisions)	> 1ng/l	<ul style="list-style-type: none"> Pro-actively inform local health professionals; continue to monitor concentrations in drinking water identify causes or sources of NDMA in drinking water
Tier 3	Regulation 4(2) (Wholesomeness)	> 10ng/l	As tier 2 plus: <ul style="list-style-type: none"> Pro-actively consult with local health professionals; put in place measures to reduce concentrations to below 10ng/l as soon as is practicable
Tier 4	Water Undertakers Information Direction 2004 (Notification of events)	>200ng/l	As tier 3 plus: <ul style="list-style-type: none"> initiate consultation with local health professionals <u>as soon as possible</u>; take action to reduce exposure from drinking water within days.

Further details describing the Inspectorate's derivation of the guidance values are given in the main body of this document.

Guidance on the Water Supply (Water Quality) Regulations 2000² specific to NDMA (N-nitrosodimethylamine) concentrations in drinking water

1. Introduction

- 1.1. The quality of drinking water in England and Wales is regulated by the Water Supply (Water Quality) Regulations 2000 (2001 in Wales), “the Regulations”. The requirements of these Regulations are enforced by the Drinking Water Inspectorate.
- 1.2. Although numerical standards are not specified for all chemical compounds in existence, the Regulations do require that, in order to be considered “wholesome”, drinking water must not contain any substance at a concentration which would constitute a potential danger to human health.
- 1.3. This document is based on a multi-tiered approach to the protection of water safety. It provides guidance on the concentrations of NDMA that water companies should act upon in order to fulfil their statutory obligations to ensure the safety of drinking water.

2. Background

- 2.1. N-nitrosodimethylamine (NDMA) is a disinfection by-product that has been classified by the United States Environmental Protection Agency (USEPA) as a probable human carcinogen. The WHO are proposing a guideline value of 100ng/l based on a lifetime exposure giving rise to a 10^{-5} cancer risk. It is understood that this value will be published in the second addendum to the third edition of the WHO guidelines. There is currently no EU standard for NDMA in drinking water and, until recently, there was little data on concentrations of NDMA in drinking water in England and Wales.
- 2.2. In 2006, DWI commissioned a research project on NDMA in drinking water to address the lack of data. The purpose of the project was to review existing data on NDMA in drinking water and to conduct a survey of NDMA concentrations in drinking waters in England and Wales. The project has recently been completed and is available on the DWI website (www.dwi.gov.uk/research).
- 2.3. The review phase identified a number of factors that were associated with formation of NDMA in drinking water. These were
 - raw water source quality (e.g. presence of organics, ammonia, nitrite);
 - proximity of discharges of sewage effluent or agricultural/industrial discharges;
 - use of treatment chemicals (i.e. amine based coagulants or polyelectrolytes);

² 2001 in Wales

- use of treatment processes (i.e. ion exchange, GAC adsorption, chloramination); and
 - distribution characteristics.
- 2.4. The monitoring phase examined water from 43 treatment works and at over 90% of these sites no detectable concentrations of NDMA were found in the final water. The concentrations of NDMA detected at the few sites where it was found were well below the proposed WHO guideline value of 100 ng/l. In fact no treated water values found were above 10ng/l. However the study identified the first evidence of iron coagulants as a possible source of NDMA and hence an additional risk factor.
- 2.5. There is no specific standard for NDMA in drinking water in England and Wales. For compounds where no numerical standard is set, the Inspectorate seeks advice from toxicological experts to determine a concentration at which drinking water does not constitute a potential danger to human health, and is therefore legally wholesome.
- 2.6. The Inspectorate received a comprehensive toxicological risk assessment from the Health Protection Agency (HPA) early in 2008. The key conclusions of this assessment were that, NDMA is a potent animal carcinogen by several routes of exposure and genotoxic both *in vitro* and *in vivo*. The HPA advised that, therefore, it should be regarded as a genotoxic carcinogen with no identifiable threshold for adverse effects and for which exposure should be reduced to as low as reasonably practicable. HPA advice was that immediate action was not required in respect of the final water concentrations that had been detected as part of the research (which were all below 10ng/l).
- 2.7. Based on the toxicological advice provided to date, the fact that drinking water is a minor source of NDMA exposure and a review of the approaches adopted by other countries, the Inspectorate's view is that water companies should adopt a multi-tiered approach to ensure the continued safety of drinking water. Guidance on this approach is detailed in section 3 below.

3. Guidance on NDMA levels in treated drinking water

3.1. In order to ensure the continued safety of drinking water, the Inspectorate expects water companies to adopt a 4-tier approach to the monitoring and management of NDMA in drinking water supplies, as outlined below.

3.2. Tier 1: Guidance on Regulation 27 – Risk assessment

3.2.1. Regulation 27 requires water companies to identify the risks to the quality of the water they supply from every treatment works and associated supply system.

Derivation

3.2.2. The Inspectorate's research programme is intended to identify new issues in relation to drinking water quality and health. It is not able to or intended to study the risks at all treatment works – this is the responsibility of the individual water companies. However the study did identify a number of risk factors for the presence of NDMA in treated water. These were listed above at paragraphs 2.3 and 2.4.

3.2.3. The monitoring phase of the research seemed to suggest that some of these factors may be less important than others in leading to NDMA formation. However, since the scope of the monitoring was limited, the precautionary approach is to assume that any of the factors may lead to NDMA formation. Companies are expected to include NDMA in their risk assessment for any supply system where iron coagulants are used and all other works which have a significant number of risk factors listed at paragraph 2.3. Companies may need to undertake monitoring in order to adequately assess risks of NDMA formation, especially where multiple hazards exist. The Inspectorate's research did not detect any seasonal trends but was based on very limited data, consequently companies' monitoring will also have to consider seasonal variations.

3.2.4. It will be important for companies to review the risk factors and their risk assessments as further data are acquired.

Action required

3.2.5. Water companies should ensure that NDMA is adequately considered in their Regulation 27 risk assessments and consider initiating monitoring for NDMA at any of their works that use iron coagulants and, based on their assessment of risk, all other works which have a significant number of risk factors listed at paragraph 2.3. Any monitoring programme should take into consideration potential season variations and the volume of water produced by the works.

3.3. Tier 2: Guidance on Regulation 10 – Sampling: further provisions (NDMA concentrations in excess of 1 ng/l)

3.3.1. Under Regulation 10 (Sampling: further provisions), in addition to the regulatory monitoring parameters, water companies are required to sample the drinking water supply for any element, organism or substance that they

have reasonable grounds for believing may cause the supply to not meet the wholesomeness requirements.

Derivation

- 3.3.2. Advice suggests that exposure to NDMA from drinking water should be kept as low as reasonably practicable. It is therefore appropriate to establish a very low trigger concentration at which sampling of drinking water supplies should be continued. A concentration of 1 ng/l has been selected because this is close to the limit that can reasonably be detected using current methods. The limit of detection reported during the bulk of the work sponsored by the Inspectorate was 0.9ng/l. The methods used in the research were GC-MS methods broadly based on the USEPA method 521 which uses GC-MSMS. Further details of the methods and their validation can be found in the research report.
- 3.3.3. The purpose of such a trigger concentration is to generate further data that would inform local community health risk assessments.

Action required

- 3.3.4. Where water companies detect concentrations of NDMA in treated drinking water supplies above 1 ng/l, they should (as a minimum):
- Continue to monitor concentrations in drinking water;
 - pro-actively inform the local health professionals (e.g. Consultants in Communicable Disease Control [CCDCs] / Directors of Public Health and Local Authority Environmental Health Officers).
 - Investigate the sources NDMA, or causes of its formation, through monitoring of different stages in the treatment processes, including into distribution.
- 3.4. Tier 3: Guidance on Regulation 4(2) wholesomeness – concentrations that may constitute a potential danger to human health (NDMA concentrations above 10ng/l)**

- 3.4.1. Regulation 4 prescribes standards of wholesomeness in respect of water supplied by water companies for cooking, drinking, food preparation and washing, and other domestic purposes, and to premises for food production purposes. Regulation 4(2) requires that, in order to be considered “wholesome”, water must not contain any substance at a level which would constitute a potential danger to human health³. The normal approach to considering standards that define wholesomeness is to consider chemicals in relation to lifetime exposure. The existing legislation means that any values above a wholesomeness level are reduced to below it as soon as is practicable. Although in some circumstances this may take some time (eg to enhance or replace a treatment process), this will certainly be well before a lifetime’s exposure is reached.

Derivation

³ The Regulations are derived from European Council Directive 98/83/EC on the quality of water intended for human consumption, which states that water intended for human consumption shall be wholesome and clean “if it is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health”

- 3.4.2. Given the toxicological profile of NDMA, HPA advise that it is not possible to identify a concentration which may not pose a potential risk, however small. However, it is important that risks from all sources are considered to understand the context of drinking water as a potential source.
- 3.4.3. The World Health Organisation (WHO) note that regular exposure to indoor tobacco smoke exceeds all other exposure by an order of magnitude. In the absence of tobacco smoke, drinking water exposure based on a mean concentration of 12ng/l is less than 10% of food based exposure, indicating that drinking water containing 10ng/l is not a major route of NDMA exposure.
- 3.4.4. WHO are proposing a guideline value of 100ng/l. This is based on the premise that lifetime exposure would give rise to a 10^{-5} cancer risk. Using the same calculation as WHO, a level of 10ng/l would correspond to a 10^{-6} cancer risk. However the models used by WHO to generate these figures, which extrapolate from high doses in animal studies to low exposures in man, differ from the approach taken by UK Government advisors. However, the HPA has advised that, for a 60 kg adult consuming 2 litres of drinking water per day at a concentration of 10 ng/l NDMA, the estimated exposure would be approximately 54,000 times below the critical cancer low effect level (lower confidence limit of the TD_{05}) identified by the WHO.
- 3.4.5. The Californian public health authority has identified 10ng/l as the concentration at which the public and local bodies should be notified, though only concentrations as high as 300ng/l need to be addressed immediately. In Germany, concentrations above 10ng/l trigger remedial action as soon as reasonably possible, and whilst these remedial actions are being taken concentrations up to 200 ng/l can be accepted for 3 years, and concentrations up to 60ng/l can be accepted for 10 years.
- 3.4.6. In order to establish guidance on the interpretation of Regulation 4(2) with respect to a concentration which may constitute a potential danger to human health, the Inspectorate has taken into consideration the toxicological advice described above, the other routes of exposure and the approaches adopted by other countries.
- 3.4.7. The Inspectorate considers that, based on current advice, it is reasonably practicable to consider concentrations of NDMA in drinking water up to 10ng/l to be compliant with the wholesomeness requirements of Regulation 4(2). Given the advice to keep exposure as low as practicable, the Inspectorate will continue to keep this guidance under review.

Action required

- 3.4.8. The Tier 3 level is the concentration above which drinking water may be considered unwholesome and water companies should therefore take positive action to discuss with local health experts what action (beyond monitoring) is appropriate to reduce exposure via drinking water supplies. This discussion should take into account the views of health experts on local community factors such as population demographics or consumer groups at particular risk, and the likely exposure to NDMA from sources other than drinking water.
- 3.4.9. Where water companies detect concentrations of NDMA in treated drinking water supplies above 10ng/l, they should (as a minimum):

- pro-actively consult with local health professionals (e.g. CCDCs / Directors of Public Health and Local Authority Environmental Health Officers) regarding strategies for reducing exposure to NDMA and related chemicals;
- put in place measures to reduce concentrations to below 10ng/l as soon as is practicable and agree a programme of work with DWI;
- monitor concentrations of NDMA in drinking water, and its sources, in order to support estimates of long term exposure.

3.5. Tier 4: Notification of events under the Information Direction 2004 (NDMA concentrations above 200ng/l)

- 3.5.1. Under the provisions of the Water Undertakers (Information) Direction 2004 ('the Direction'), water companies are required to notify the Inspectorate of any event, which by its nature has adversely affected or is likely to adversely affect the quality or sufficiency of the water supplied.
- 3.5.2. In addition to any notifications triggered by an exceedance of the "tier 3" concentration above, it is also appropriate to determine a NDMA concentration that would require urgent intervention (and notification of relevant stakeholders).
- 3.5.3. The WHO concluded that, as a consequence of the clear evidence of carcinogenicity, there have been few studies of other possible toxic end points. WHO therefore decided that the existing data are inadequate to quantify the health risk for NDMA by any endpoint other than carcinogenicity.

Derivation

- 3.5.4. In light of the conclusion reached by WHO, it seems sensible to establish any short term exposures limits on the same carcinogenicity endpoint.
- 3.5.5. The Californian response level (300ng/l) is based a 10^{-4} risk of cancer, derived by low dose extrapolation from animal data.
- 3.5.6. In Germany concentrations up to 200 ng/l can be accepted for 3 years, and concentrations up to 60ng/l can be accepted for 10 years provided steps are in place to reduce level below 10 ng/l as soon as reasonably possible. These levels are derived by low dose extrapolation from animal data and correspond to an additional lifetime risk by NDMA which is in total not higher than 5×10^{-6} . Moreover, they contain a supplementary safety margin to cope with the possibility that infants and children (up to 10 years) may be up to ten times more susceptible to genotoxic compounds than adults. Further details of the derivation is given in documents that can be found on the website. <http://www.umweltbundesamt.de/wasser-e/themen/drinking-water/empfehlungen.htm>
- 3.5.7. Given the overall toxicity for the compound, and based on advice from the HPA, the Inspectorate advocates taking a precautionary approach and setting a level of 200ng/l.
- 3.5.8. The Inspectorate's view is that, notwithstanding any action taken in response to an exceedance of the "tier 3" concentration, water companies should

initiate their notification arrangements under the Direction at a NDMA concentration that is greater than 200ng/l.

Action required

3.5.9. Where water companies detect NDMA concentrations in excess of 200ng/l, the Inspectorate expects companies to initiate consultation with local health professionals (CCDCs / Directors of Public Health and Local Authority EHOs) as soon as possible and to take urgent action to reduce exposure from drinking water within a matter of days. Further action would then be required to reduce concentrations to below 10ng/l as soon as practicable.

Water unfit for human consumption

3.5.10. As with all notifications received under the Information Direction 2004, the Inspectorate will investigate further and consider whether there are grounds for initiating a prosecution for the offence of supplying water unfit for human consumption under section 70 of the Water Industry Act 1991.

3.5.11. It is important to note that although the Chief Inspector of Drinking Water can initiate prosecution proceedings for the offence of supplying water unfit for human consumption, the decision as to whether any such offence had been committed would be made by a court.

3.5.12. In conducting any investigation into a potential offence for the supply of water unfit for human consumption, the Inspectorate will take into account toxicological advice available to it.

4. Other nitrosamines

4.1. NDMA is just one of a number of nitrosamines that may be genotoxic carcinogens. Where NDMA is detected in the final water companies would be prudent to monitor for other nitrosamines that may be present.

4.2. Should other nitrosamines be detected, companies are expected to take the steps they would normally take to fulfil their statutory duties following detection of any contaminant, such as conducting further investigations and consulting with local health advisors.

5. On-going work on NDMA

5.1. *Drinking water research on NDMA*

The Inspectorate has commissioned further research into this issue. This further work has two aims

1) to determine whether NDMA is present in iron and aluminium coagulants currently used in England and Wales.

2) to look more closely at the factors that may form or remove NDMA during water treatment

The Inspectorate will keep the industry updated on the findings of this work.

5.2. *Investigation in to the presence of NDMA in coagulants*

The Inspectorate has already notified the manufacturer of the products which appear to contain NDMA of the findings of the research and encouraged it to take whatever steps are necessary to ensure that NDMA is not present in the products. The manufacturer has made a very positive response to the

Inspectorate's findings. It has completed an investigation of NDMA levels in its products which broadly confirmed the Inspectorate's findings. It found NDMA arose in its production process as a result of the use of a particular additive, which the manufacturer has now eliminated from its process. It has completed a successful works scale operations trial without using the additive. That trial demonstrated a permanent reduction in the levels of NDMA in its products. The company has now implemented these changes permanently.

- 5.3 *Potential future regulatory action in respect of water treatment products*
Notwithstanding the advice given in section 3 above, the Inspectorate considers that, in line with HPA advice and in order to keep risk to a minimum, the concentration of NDMA in treatment products should be as low as practicable and ideally products should be essentially free from NDMA. Accordingly when the results of future research are available the Inspectorate will be consider whether action under regulation 31 is appropriate.

**Drinking Water Inspectorate
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