Guidance on the Water Supply (Water Quality) Regulations 2000[1] specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) concentrations in drinking water

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[1] 2001 in Wales

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Summary

Perfluorooctane sulphonate (PFOS) and Perfluorooctanoic acid (PFOA) are perfluorinated chemicals which may be found in substances used in the chromium plating, photography and photolithography industries, as well as in certain fire-fighting foams and hydraulic aviation fluids. Historically these compounds have also been used in providing grease, oil and water resistance to materials such as textiles, carpets and paper.

Although the Inspectorate is not aware of PFOS or PFOA being found at levels which would cause concern in drinking water in England or Wales, the persistent nature of these compounds and the wide variety of potential sources are such that 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 levels of PFOS and PFOA 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	Guidance value (concentration)	Minimum action to be taken
Perfluorooctane sulphonate (PFOS)			
Tier 1	Regulation 27 (Risk assessment)	potential hazard	• ensure considered as part of statutory risk assessment
Tier 2	Regulation 10 (Sampling: further provisions)	> 0.3µg/l	• consult with local health professionals; • monitor levels in drinking water.
Tier 3	Regulation 4(2) (Wholesomeness)	> 1.0µg/l	As tier 2 plus: • put in place measures to reduce concentrations to below 1.0µg/l as soon as is practicable.
Tier 4*	Water Industry (Suppliers' Information Direction) 2009 (Notification of events)	> 9.0ug/l	As tier 3 plus: • ensure consultation with local health professionals takes place as soon as possible; • take action to reduce exposure from drinking water within 7 days.
*Note - notification to the Inspectorate under the Information Direction may also be triggered at lower levels due to Tier 1, 2 or 3 activities			
Perfluorooctanoic acid (PFOA)			
Tier 1	Regulation 27 (Risk assessment)	potential hazard	• ensure considered as part of statutory risk assessment
Tier 2	Regulation 10 (Sampling: further provisions)	> 0.3µg/l	• consult with local health professionals; • monitor levels in drinking water.
Tier 3	Regulation 4(2) (Wholesomeness)	> 5.0µg/l	As tier 2 plus: • put in place measures to reduce concentrations to below 5.0µg/l as soon as is practicable.
Tier 4*	Water Industry (Suppliers' Information Direction) 2009 (Notification of events)	> 45.0µg/l	As tier 3 plus: • ensure consultation with local health professionals takes place as soon as possible; • take action to reduce exposure from drinking water within 7 days.
*Note - notification to the Inspectorate under the Information Direction may also be triggered at lower levels due to Tier 1 2 or 3 activities			

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 2000/01 specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) 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 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 level 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 levels of PFOS and PFOA that water companies should act upon in order to fulfil their statutory obligations to ensure the safety of drinking water.

2. Background (PFOS & PFOA)

2.1. Perfluorooctane sulphonate (PFOS) and perfluorooctanoic acid (PFOA) are perfluorinated chemicals and commercially available in the form of salts, derivatives and polymers. PFOS has been identified as being persistent, bio-accumulative in the environment and toxic in terms of human health.

2.2. Historically the major uses for PFOS-related substances were in providing grease, oil and water resistance to materials such as textiles, carpets, paper and in general coatings but industry has now moved away from such uses. The current uses are in chromium plating, photography, photolithography, fire-fighting foams and in hydraulic fluids for aviation. In December 2006 the European Parliament passed Directive 2006/12/EC restricting the marketing and use of PFOS[2].

2.3. Although the Inspectorate is not aware of PFOS or PFOA being found at levels which would cause concern in drinking water in England or Wales, the persistent nature of these compounds and the wide variety of potential sources are such that the Inspectorate considers it appropriate to provide specific guidance to water companies.

2.4. There is no specific standard for either PFOS or PFOA in drinking water in England and Wales. For compounds where no standard is set, the Inspectorate seeks advice from independent toxicological experts to determine a level at which drinking water does not constitute a potential danger to human health, and is therefore legally wholesome.

2.5. On receipt of an initial toxicological assessment of PFOS by the Health Protection Agency (HPA) early in 2006, the value of 3µg/l (microgrammes per litre) was provided by the Inspectorate to water companies as reflecting the best available evidence on which a water company could base its judgement of wholesomeness.

[2] Official Journal of the European Union - L372 p.32-34 (27.12.2006)

2.6. In January, February and March 2007 the HPA provided further advice on both PFOS and PFOA. This revised advice included consideration of the statement by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) about the Tolerable Daily Intakes (TDI: an estimate of the amount of a substance in food and drinking water that can be ingested over a lifetime without appreciable risk) for PFOS and PFOA, and the Food Standards Agency's work on UK dietary intakes of fluorinated chemicals. Due to the complexity of the issue and the uncertainties involved, the Inspectorate also sought further advice from an independent toxicological consultant.

2.7. In July 2009 the COT reconsidered its advice on PFOA in light of the European Food Safety Authority (EFSA) and the US Environmental Protection Agency (US EPA) derivations of a TDI and a Provisional Health Advisory Value, respectively. Both EFSA and the USEPA used the same toxicity endpoint but employed different uncertainty factors in deriving their health guidelines. In summary, the COT agreed with the TDI of 1.5 µg/kg bw recommended by EFSA. The COT also considered that this should remain provisional and be reviewed as new information becomes available. The COT considered that, on the basis of available information, this provisional TDI is adequate to protect against the range of identified toxic effects caused by PFOA. The COT's full statement can be found at http://cot.food.gov.uk/pdfs/cotstatementpfoa200902.pdf. As part of this review, the COT also reconsidered the TDI for PFOS and confirmed that its previous advice remained appropriate.

2.8. Based on the toxicological advice provided to date, and the acknowledged uncertainties in the data on which assessments of PFOS exposure are based, 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 sections 3 and 4 below.

3. Guidance on PFOS 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 PFOS 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.

3.2.3 The Inspectorate's research on PFOS and PFOA failed to find levels which would cause concern in drinking water in England or Wales. However, since the scope of the monitoring was limited, Companies are expected to include PFOS in their risk assessment for any supply system where they consider a potential PFOS hazard to the water supply system may be present (for example the uses identified in paragraph 2.2). Companies may need to undertake monitoring in order to adequately assess risks of PFOS, especially where multiple hazards exist.

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 PFOS is adequately considered in their Regulation 27 risk assessments and consider initiating monitoring for PFOS at any of their works where appropriate.

3.3. Tier 2: Guidance on Regulation 10 – Sampling: further provisions (PFOS concentrations in excess of 0.3µg/l)

3.3.1. Water companies are responsible for identifying risks to the quality of the water they supply. 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 to believe may cause the supply not to be wholesome.

Derivation

3.3.2. Advice suggests that in a worst-case scenario, where exposure from other sources is higher than the provisional Tolerable Daily Intake, then PFOS exposure from drinking water should be kept as low as reasonably practicable. It is therefore appropriate to establish a trigger level at which further sampling of drinking water supplies should be initiated.

3.3.3. The purpose of such a trigger level is to generate data that would inform local community health risk assessments.

3.3.4. Toxicological advice suggests that a PFOS concentration of 0.3µg/l is a reasonable level above which action should be taken (based on the allocation of 10% of the provisional TDI to 1 litre of drinking-water consumed daily by a one-year-old child weighing 10kg).

Action required

3.3.5. Where water companies detect levels of PFOS in treated drinking water supplies above 0.3µg/l, they should (as a minimum):

- monitor levels in drinking water in order to support estimates of long term exposure to PFOS and related chemicals;
- consult with local health professionals (e.g. Consultants in Communicable Disease Control [CCDCs] / Directors of Public Health and Local Authority Environmental Health Officers).

3.4. Tier 3: Guidance on Regulation 4(2) wholesomeness – concentrations that may constitute a *potential* danger to human health (PFOS concentrations above 1.0µg/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 health[3]. In considering the potential danger to human health element of wholesomeness, it is important to consider chemicals in relation to lifetime exposure (see 3.4 below for short-term exposure issues).

Derivation

3.4.2. Taking into consideration the worst case estimates of dietary intakes of PFOS for a small adult, advice suggests that up to 3.0µg/l in drinking water would still ensure that exposure in adults remains below the provisional Tolerable Daily Intake. However, the Inspectorate understands that there is considerable uncertainty in estimates of dietary exposure to PFOS for young children. Uncertainty in the dietary exposure estimates means there is also uncertainty in the proportion of the TDI that can be allocated to drinking water. Consequently childhood exposure from drinking water may be appropriately restricted by establishing a value in the range zero and 2.5µg/l.

3.4.3. In order to establish guidance on the interpretation of Regulation 4(2) with respect of a concentration which may *potentially* be harmful to human health, the Inspectorate

[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"

has taken into consideration the toxicological advice described above, and the acknowledged uncertainties in estimates of exposure to PFOS from other sources.

3.4.4. The Inspectorate considers that, based on current advice, it is reasonably practicable to consider concentrations of PFOS in drinking water up to 1.0µg/l as meeting the wholesomeness requirements of Regulation 4(2).

Action required

3.4.5. The Tier 3 level is the concentration above which drinking water may be unwholesome and water companies should therefore take 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. For example, a typical action to be considered may be the provision of alternative supplies (bottled water or similar) to children in the affected area.

3.4.6. Where water companies detect levels of PFOS in treated drinking water supplies above 1.0µg/l, they should (as a minimum):

- consult with local health professionals (e.g. CCDCs / Directors of Public Health and Local Authority Environmental Health Officers) regarding strategies for reducing exposure to PFOS and related chemicals;
- put in place measures to reduce concentrations to below 1.0µg/l as soon as is practicable;
- monitor levels in drinking water in order to support estimates of long term exposure to PFOS and related chemicals.

3.5. Tier 4: Notification of events under the Information Direction 2009 (PFOS concentrations above 9.0µg/l)

3.5.1. Under the provisions of the Water Industry (Suppliers' Information Direction) 2009 ('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. The nature of environmental contamination by PFOS is such that there is a potential for it to reach drinking water sources with little prior warning. In addition to any notifications triggered by an exceedance of the "tier 2" or "tier 3" concentrations above, it is also appropriate to determine a PFOS concentration that would require more immediate intervention (and notification of relevant stakeholders).

3.5.3. Toxicological advice provided to the Inspectorate has identified concentrations of PFOS which may result in acute health impacts from short-term exposure. Such concentrations *may* be considered by a court to constitute water which is unfit for human consumption (see sections 3.5.6 – 3.5.8 below). However, in order to minimise consumer exposure, the Inspectorate advocates a precautionary approach. The Inspectorate's view is that companies should initiate their notification arrangements at PFOS concentrations well below a level which may cause the water supply to be potentially unfit for human consumption.

Derivation

3.5.4. The Inspectorate's view is that not withstanding any action taken in response to an exceedance of the "tier 2" or "tier 3" concentrations, water companies should initiate their notification arrangements under the Direction at a PFOS concentration that is greater than the equivalent of allocating of all of the provisional Tolerable Daily Intake to drinking water in an adult, i.e. > 9.0µg/l.

Action required

3.5.5. Where water companies detect PFOS concentrations in excess of 9.0µg/l, the Inspectorate expects companies to ensure consultation with local health professionals (CCDCs / Directors of Public Health and Local Authority EHOs) takes place as soon as possible, and to take action to reduce exposure from drinking water within 7 days. Further action will then be required to reduce concentrations to below 1.0µg/l as soon as practicable.

Water unfit for human consumption

3.5.6. As with all notifications received under the Information Direction 2009, the Inspectorate will investigate 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 and/or other offences under the Water Supply (Water Quality) Regulations 2000/01 (as amended).

3.5.7. It is important to note that although the Chief Inspector of Drinking Water can decide that it is in the public interest to initiate proceedings for the offence of supplying water unfit for human consumption, the decision (as to whether any such offence had been committed) is for the courts to make.

3.5.8. In conducting any investigation into a potential offence for the supply of water unfit for human consumption, the Inspectorate will take into account the most recent toxicological advice available. Currently the Inspectorate understands that drinking water at the following PFOS concentrations might result in adverse effects on, or relatively soon after exposure:

- 67µg/l for bottle-fed babies;
- 100µg/l for 1 year old children;
- 300µg/l for adults.

4. Guidance on PFOA levels in treated drinking water

4.1. In line with the guidance for PFOS, the Inspectorate also expects water companies to adopt a 4-tier approach to the monitoring and management of PFOA in drinking water supplies, as outlined below.

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

4.2.1. 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

4.2.2. 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.

4.2.3. Except for a single sample, the Inspectorate's research on PFOS and PFOA failed to find levels of PFOA above the trigger values in this document. However, since the scope of the monitoring was limited, Companies are expected to include PFOA in their risk assessment for any supply system where they consider a potential PFOA hazard to the water supply system may be present (for example uses identified in paragraph 2.2). Companies may need to undertake monitoring in order to adequately assess risks of PFOA, especially where multiple hazards exist.

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

Action required

4.2.5. Water companies should ensure that PFOA is adequately considered in their Regulation 27 risk assessments and consider initiating monitoring for PFOA at any of their works where appropriate.

4.3. Tier 2: Guidance on Regulation 10 – Sampling: further provisions (PFOA concentrations in excess of 0.3µg/l)

Derivation

4.3.1. In determining guidance on Regulation 10 (Sampling: further provisions) the Inspectorate's view is that, whilst the Tolerable Daily Intake for PFOA is higher than for PFOS, and dietary exposure less significant, the detection of PFOA at elevated concentrations may indicate a potential source of other perfluorinated chemicals.

4.3.2 Thus, in the absence of information to the contrary, further sampling and investigation is appropriate at a comparable concentration to that for PFOS i.e. >0.3µg/l.

4.3.3. The purpose of such a trigger level is to generate data that would inform local community health risk assessments

Action required

4.3.4. Where water companies detect levels of PFOA in treated drinking water supplies above 0.3µg/l, they should (as a minimum):

- monitor levels in drinking water in order to support estimates of long term exposure to PFOA and related chemicals;

- consult with local health professionals (e.g. CCDCs / Directors of Public Health and Local Authority Environmental Health Officers.

4.4. Tier 3: Guidance on Regulation 4(2) wholesomeness – concentrations that may constitute a *potential* danger to human health (PFOA concentrations above 5.0µg/l)

4.4.1. 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 health[4]. When considering "potential danger to human health" it is important to consider chemicals in relation to lifetime exposure (see 4.5 below for short-term exposure issues).

Derivation

4.4.2. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has recently re-evaluated PFOA and has proposed a Tolerable Daily Intake (TDI) of 1.5 µg/kg body weight per day for PFOA. The Inspectorate understands that the dietary intake study suggested that exposure to PFOA from foodstuffs was significantly lower than for PFOS.

4.4.3. There are no estimates of dietary intake of PFOA for very young children. Assigning 50% of the TDI to drinking water for a 5kg bottle fed infant consuming 0.75 l/day equates to a drinking water concentration of 5 µg/l. At this concentration the estimated total intake (from diet and water) would be lower than the TDI for all groups for which dietary estimates are available. A concentration of 5 µg/l would therefore be protective for the whole age range of consumers.

4.4.4. The Inspectorate considers that, based on current advice, it is reasonably practicable to consider concentrations of PFOA in drinking water of 5.0µg/l or less as meeting the wholesomeness requirements of Regulation 4(2).

Action required

4.4.5. The Tier 3 level is the concentration above which drinking water may be unwholesome and water companies should therefore take 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

[4] 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"

groups at particular risk. For example, a typical action to be considered may be the provision of alternative supplies (bottled water or similar) to vulnerable consumers in the affected area.

4.4.6. Where water companies detect levels of PFOA in treated drinking water supplies above 5.0µg/l, they should (as a minimum):

- consult with local health professionals (e.g. CCDCs / Directors of Public Health and Local Authority Environmental Health Officers) regarding strategies for reducing exposure to PFOA and related chemicals;
- put in place measures to reduce concentrations to below 5.0µg/l as soon as is practicable;
- monitor levels in drinking water in order to support estimates of long term exposure to PFOA and related chemicals.

4.5. Tier 4: Notification of events under the Information Direction 2009 (PFOA concentrations above 45 µg/l)

4.5.1. Under the provisions of 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.

4.5.2. As with PFOS, the nature of environmental contamination by PFOA is such that there is a potential for it to reach drinking water sources with little prior warning. In addition to any notifications triggered by an exceedance of "tier 2" or "tier 3" concentrations above, it is also appropriate to determine a PFOA concentration that would require more immediate intervention and notification of relevant stakeholders.

4.5.3. Toxicological advice provided to the Inspectorate has identified concentrations of PFOA which may result in acute health impacts from short-term exposure. Such concentrations *may* constitute water which is unfit for human consumption (see sections 4.5.6 – 4.5.8 below). However, in order to minimise consumer exposure, the Inspectorate advocates a precautionary approach. The Inspectorate's view is that companies should initiate their notification arrangements at PFOA concentrations significantly below those which may result in water being potentially unfit for human consumption.

Derivation

4.5.4. The Inspectorate's view is that not withstanding any action taken in response to an exceedance of the "tier 2" or "tier 3" concentrations, water companies should initiate their notification arrangements under the Direction at a PFOA concentration that is greater than the equivalent of allocating of all of the provisional Tolerable Daily Intake to drinking water in an adult i.e. 45 µg/l.

Action required

4.5.5. Where water companies detect PFOA concentrations in excess of 45 µg/l, the Inspectorate expects companies to ensure consultation with local health professionals (CCDCs / Directors of Public Health and Local Authority EHOs) takes

place as soon as possible, and to take action to reduce exposure from drinking water within 7 days. Further action will then be required to reduce concentrations to below 5.0µg/l as soon as practicable.

Water unfit for human consumption

4.5.6. As with all notifications received under the Information Direction 2009, the Inspectorate will investigate 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 and/or other offences under the Water Supply (Water Quality) Regulations 2000/01 (as amended).

4.5.7. It is important to note that although the Chief Inspector of Drinking Water can initiate proceedings for the offence of supplying water unfit for human consumption, the decision as to whether any such offence had been committed is for the courts to decide.

4.5.8. 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 at that time. Currently the Inspectorate understands that drinking water at the following PFOA concentrations might result in adverse effects on, or relatively soon after exposure:

- 2mg/l (2000µg/l) for bottle-fed babies;
- 3mg/l (3000µg/l) for 1 year old children;
- 9mg/l (9000µg/l) for adults.

5. Other perfluorinated chemicals

5.1. PFOS and PFOA form part of a large group of perfluorinated chemical substances. Where the toxicity of such chemicals is unknown, the Inspectorate would expect water companies to adopt a precautionary approach based on that described above for PFOS which has known persistent, bioaccumulative and toxic properties.

6. On-going work on perfluorinated chemicals

6.1. *Dietary exposure to PFOS & PFOA*

The Inspectorate understands that the Food Standards Agency is conducting studies into the presence of fluorinated chemicals in various foodstuffs to further understand the concentrations occurring in the foodstuffs.

6.2. *Environmental sources of PFOS & PFOA*

Following work carried out by Defra, to propose restrictions on the marketing and use of PFOS and substances that degrade to PFOS in the UK, action is being taken to remove the primary sources of contamination, through the adoption of the European Directive restricting the marketing and use of PFOS[5]. In addition, the Environment Agency is carrying out sampling of environmental ground and surface waters to further understand the occurrence of PFOS and PFOA in the water environment.

6.3. *Drinking water research on PFOS & PFOA*

Research commissioned by the Inspectorate, indicates that neither PFOS nor PFOA appears to be a widespread contaminant of raw and treated drinking water in England. In respect of PFOS, where low levels were detected they were below the trigger values in this document and only at sites already identified as high risk. In respect of PFOA, only a single sample exceeded the Tier 2 level (0.3µg/l) and this concentration was not observed in subsequent samples from the same site. This research does therefore highlight the importance of water companies carrying out local risk assessments of their catchments & water supply systems as they are now required to do under the regulations

The Inspectorate continues to liaise with the Environment Agency and the water industry (WaterUK), on water related research into PFOS and PFOA to facilitate the sharing of information and to gain maximum benefit from the resources deployed.

Drinking Water Inspectorate
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[5] Official Journal of the European Union - L372 p.32-34 (27.12.2006)