



Guidance on the Water Supply (Water Quality) Regulations 2016¹ specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) concentrations in drinking water

DRINKING WATER INSPECTORATE

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¹ As amended

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Summary

Perfluorooctane sulphonate (PFOS) and Perfluorooctanoic acid (PFOA) are perfluorinated chemicals which historically have had a wide range of uses including polymer precursors, certain fire-fighting foams and providing grease, oil and water resistance to materials such as textiles, carpets and paper. Increasing restrictions since 2004 in the UK and Europe have meant that very few uses of PFOS currently remain permitted. Restrictions on PFOA are more recent with some time limited exemptions remaining.

Since this guidance was last revised, in October 2009, more information on the toxicity of these compounds has become available and therefore it is appropriate to revise the thresholds. The data that are available for the UK and Europe suggest that level of PFOS and PFOA in surface waters range from sub/low ng/L levels to 10s of ng/L (1ng/L = 0.001µg/L) 1. Some groundwater in high risk areas may have higher levels and may be affected by this guidance.

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 consider when fulfilling their statutory obligations to ensure the safety of drinking water. Like all DWI guidance, this document does not purport to offer definitive interpretation of the relevant Regulations. 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	<ul style="list-style-type: none"> ensure considered as part of statutory risk assessment
Tier 2	Regulation 10 (Sampling: further provisions)	> 0.01µg/L	<ul style="list-style-type: none"> consult with local health professionals; monitor levels in drinking water.
Tier 3	Regulation 4(2) (Wholesomeness)	> 0.1µg/L	As tier 2 plus: <ul style="list-style-type: none"> put in place measures to reduce concentrations to below 0.1µg/L as soon as is practicable.
Tier 4*	Water Industry (Suppliers' Information) Direction 2020 (Notification of events)	> 1.0µg/L	As tier 3 plus: <ul style="list-style-type: none"> ensure consultation with local health professionals takes place <u>as soon as possible</u>; 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	<ul style="list-style-type: none"> ensure considered as part of statutory risk assessment
Tier 2	Regulation 10 (Sampling: further provisions)	> 0.01µg/L	<ul style="list-style-type: none"> consult with local health professionals; monitor levels in drinking water.
Tier 3	Regulation 4(2) (Wholesomeness)	> 0.1µg/L	As tier 2 plus: <ul style="list-style-type: none"> put in place measures to reduce concentrations to below 0.1 µg/L as soon as is practicable.
Tier 4*	Water Industry (Suppliers' Information) Direction 2020 (Notification of events)	> 1.0µg/L	As tier 3 plus: <ul style="list-style-type: none"> ensure consultation with local health professionals takes place <u>as soon as possible</u>; 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 2016 (as amended) specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) concentrations in drinking water

1. Introduction

- 1.1. The quality of public drinking water supplies in England and Wales is regulated by the Water Supply (Water Quality) Regulations 2016 (as amended) and the Water Supply (Water Quality) Regulations 2018 respectively [“the Regulations”]. The requirements of these Regulations are enforced by the Drinking Water Inspectorate (“the Inspectorate”).
- 1.2. Although standards are not specified for all chemical compounds in existence, the Regulations do require that, in order to be regarded as “wholesome”, drinking water must not contain any substance at a level which would constitute a potential danger to human health (as well as meeting the other requirements of the Regulations).
- 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 consider when fulfilling 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 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 only currently permitted use in the EU is as a mist suppressant for non-decorative hard chromium (VI) plating in closed loop systems.
- 2.3. PFOA and its ammonium salt (APFO) were identified as substances of very high concern (SVHC) under the REACH Regulation in July 2013 because of their persistent, bio-accumulative and toxic (PBT) properties. They were restricted in the EU after 4th July 2020, with some time-limited exemptions such as for protective textiles and fire-fighting foams.
- 2.4. 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. Currently levels in surface waters range from sub/low ng/L to 10s of ng/L (1 ng/L = 0.001 µg/L). Some groundwater in high risk areas may have levels exceeding 100 ng/L and if so, would be affected by this guidance.
- 2.4. There is no specific standard listed in the Regulations for either PFOS or PFOA in drinking water in England and Wales. For compounds where no standard is set, the Inspectorate seeks advice from Public Health England (PHE) and, if appropriate, other independent toxicological experts to determine a level at which drinking water does not constitute a potential danger to human health, and therefore could be regarded as wholesome.

- 2.5. The first edition of this guidance, issued in May 2007, established a tiered approach to the regulation of these substances with wholesomeness thresholds at 1.0 µg/L for PFOS and 10 µg/L for PFOA. These values were based on advice from the Health Protection Agency (the predecessor body to PHE), the considerations of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and due to the complexity of the issue and the uncertainties involved, further advice from an independent toxicological consultant.
- 2.7. The second edition of this guidance, dated October 2009, retained the same approach but reduced the wholesomeness threshold for PFOA to 5 µg/L. This change was based on reconsideration by the COT, its advice on PFOA in light of the European Food Safety Authority (EFSA) and the US Environmental Protection Agency (US EPA) derivations of a Tolerable Daily Intake (TDI) and a Provisional Health Advisory Value, respectively. In summary, the COT agreed with the TDI of 1.5 µg/kg-bodyweight (bw) for PFOA recommended by EFSA. This was a reduction from the previous TDI of 3 µg/kg bw. As part of this review, the COT also reconsidered the TDI for PFOS and confirmed its previous advice which set the PFOS TDI at 0.3 µg/kg bw. Further details of the COT consideration can be found here: <https://cot.food.gov.uk/sites/default/files/cot/cotstatementpfoa200902.pdf>
- 2.8. Since 2009 more data have become available on the toxicity of PFOS and PFOA and whilst there are significant differences in the interpretation of these data by different authoritative bodies, the critical endpoints and TDIs established are consistently lower than those from 2009. The differences for PFOS can be illustrated by the approaches taken by EFSA and Health Canada. In 2018, EFSA proposed a provisional TDIs of 1.8 ng/kg bw for PFOS based on effects on serum cholesterol from human studies, whereas Health Canada established a TDI of 60ng/kg bw based on animal studies (liver effects in rats). Similarly, for PFOA, EFSA proposed a provisional TDIs of 0.8 ng/kg bw based on effects on serum cholesterol from human studies, whereas Australian authorities established a TDI of 160ng/kg bw based on animal studies (fetal toxicity in mice).

2.9 A summary of the different approaches is given in the table below

Body	Substance	endpoint	UF	TDI or similar	Drinking water standard
EFSA 2008	PFOS	NOEL 0.03mg/kg bw Monkey study reduction in serum lipids and T3	200	TDI 0.15 µg/kg bw	
	PFOA	BMDL 10	200	TDI 1.5 µg/kg bw	

		0.3mg/kg bw Liver weight in rats			
COT 2009	PFOS	NOAEL 0.03mg/kg bw Monkey study serum T3 levels	100	TDI 0.3 µg/kg bw	DWI guidance 1 µg/L No exact derivation
	PFOA	As EFSA	200	TDI 1.5 µg/kg bw	DWI guidance 5 µg/L 50% RSA, 5kg infant 0.75L/day
USEPA 2016	PFOS	HED 0.00051 mg/kg bw based on NOAEL 0.1mg/kg/d for reduced pup weight in rat	30	RfD = 0.02 µg/kg/day	Health advisory 0.07 µg/L (RSA 20% 0.054L/kg)
	PFOA	HED 0.0053 mg/kg bw based on LOAEL 1mg/kg/d for reduced ossification in mice	300	RfD = 0.02 µg/kg/day	Health advisory 0.07 µg/L (RSA 20% 0.054L/kg)
Foods Standards Australia New Zealand 2017	PFOS and PFHxS	HED 0.0006 mg/kg/d NOAEL 0.1mg/kg/d decreased body weight gains in rats	30	TDI 0.02 µg/kg	0.070 µg/L (70kg adult 2L/d and RSA 10%)

	PFOA	HED 0.0049 mg/kg/d NOAEL 1 mg/kg/d for fetal toxicity in study in mice	30	TDI 0.16 µg/kg	0.560 µg/L (70kg adult 2L/d and RSA 10%)
EFSA 2018	PFOS	BMDL 05 22ng/mL Human serum cholesterol	PBPK	PTDI 0.0018µg/kg bw PTWI 0.013µg/kg bw	
	PFOA	BMDL 05 9.2ng/mL Human serum cholesterol	PBPK	PTDI 0.0008µg/kg bw PTWI 0.006µg/kg bw	
Health Canada 2018	PFOS	HE POD 0.0015 mg/kg/d NOAEL 0.021 mg/kg/d liver effects in rats	25	TDI 0.06 µg/kg bw	0.6 µg/L (70 kg adult, 1.5L/d, RSA 20%)
	PFOA	HE POD 0.000521 mg/kg bw/d BMDL10 of 0.05 mg/kg bw per day liver effects in rats	25	TDI 0.019 µg/kg bw	0.2 µg/L (70 kg adult, 1.5L/d, RSA 20%)
EFSA 2020	PFOS, PFOA, PFNA, PFHxS	NOAEC of 31.9 ng/mL Based on antibody	PBPK to generate intake by mother of 1.16	TWI 0.008µg/kg	

		titres against haemophilus influenzae type b in 1 year olds	ng/kg/day		
COT 2020	<p>In the COT initial consideration two of the key papers on immune response used by EFSA 2020. It concluded breastfed infants in the UK could be receiving levels of up to approximately 100-fold the TWI. However, these are environmental contaminants that cannot be removed from the diet. A reduction in antibody response would have serious health consequences, but it is not known what the threshold is for this effect and there does not appear to be any evidence in the general population that vaccine efficacy is being impaired in the UK. Indeed, vaccination programmes have led to the successful eradication of some diseases.</p> <p>Whilst the COT are unable to suggest an alternative TWI at this time, there will need to be strong caveats explaining the exposure estimates versus TWI relative to exposures and these would need to be considered carefully to avoid miscommunication of the data. COT will consider the EFSA evaluation further.</p>				
WHO	<p>WHO Europe made recommendations to the Commission for these substances as part of the review process of the EU Drinking Water Directive. Values of 0.4 µg/L for PFOS and 4.0 µg/L for PFOA were suggested. These substances will form part of the WHO guidelines review process but no values have been set as yet.</p>				

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 tiered 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. This clearly places the responsibility on the individual water companies to assess the risks at all treatment works.

3.2.2 Companies should include a consideration of whether levels of PFOS constitute a potential danger to human health or are likely to be unwholesome in their risk assessment. As most of the uses of PFOS are now prohibited, companies will have to use local knowledge to understand the historic uses in the catchments they abstract from. This knowledge can be supplemented by and refined in light of the companies' own raw water monitoring, data from the Environment Agency and, in respect of surface water, data gathered under the industry's collaborative Chemical Investigation Programme (CIP). Companies may need to undertake monitoring in order to adequately assess risks of PFOS, especially where multiple hazards exist.

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

Action advised

3.2.4 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 0.01 µg/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 of 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. Given the variation in interpretation of the toxicological data and uncertainty over exposure to PFOS via other routes and the desire to minimise exposure from drinking water, a pragmatic approach has been adopted to establish a trigger level for further sampling. A threshold of 0.01 µg/L is proposed as a level that can be reliably and accurately measured using modern analytical techniques.

- 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. This trigger is well below toxicological based standards established in the US, Canada and Australia that are considered to pose no significant risk to health from long-term exposure.

Action advised

- 3.3.5. Where water companies detect levels of PFOS in treated drinking water supplies above 0.01 µg/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 0.1 µg/L)

- 3.4.1. Regulation 4 prescribes standards of wholesomeness in respect of water supplied by water companies that is intended for human consumption including for such domestic purposes as include cooking, drinking, food preparation and washing or for food production purposes. Regulation 4(2) requires (*inter alia*) that, in order to be regarded as “wholesome”, water must not contain any substance at a level which would constitute a potential danger to human health². In considering the potential danger to human health element of wholesomeness, it is important to consider chemicals in relation to lifetime exposure.

Derivation

- 3.4.2. The February 2018 proposal, from the EU Commission, to revise the Drinking Water Directive included a proposed standard for any individual PFAS of 0.1 µg/L and 0.5 µg/L for total PFAS. These values are more stringent than the recommendation made by the World Health Organisation (WHO) to the Commission of 0.4µg/L for PFOS. The Commission likened the values in the proposal to the pesticide standard and noted that whilst above US and Swedish value were described as feasible to meet.
- 3.4.3 The final text of the Directive, agreed by European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) on the 18 February 2020 and the European Council at the Environment Council on 5 March 2020, includes an even

² 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”

more stringent standard of 0.1 µg/L for the sum of 20 named PFAS and retains 0.5µg/L for total PFAS.

- 3.4.3. In order to establish guidance on the interpretation of Regulation 4(2) with respect of a concentration which may be a potential danger to human health, the Inspectorate has taken into consideration the recent toxicological reviews described above, and the acknowledged uncertainties in estimates of exposure to PFOS from other sources and the present knowledge of levels in water.
- 3.4.4. The Inspectorate considers that it is reasonably practicable to consider concentrations of PFOS in drinking water up to 0.1 µg/L as meeting the wholesomeness requirements of Regulation 4(2). This value is well below the WHO advice to the Commission though above the USEPA health advisory. A value of 0.1 µg/L corresponds to a daily intake of 3.3ng/kg bw for a 60 kg adult drinking 2L per day and 0.01 µg/kg bw for a 10kg infant drinking 1 L per day. These intakes generally correspond to only a fraction of TDI that have been established by authoritative bodies (see table below). The exception is the PTDI proposed by EFSA in 2018 derived using a physiologically based pharmacokinetic (PBPK) model from the BMDL for a 5% increase in serum cholesterol. The 2020 EFSA consultation raised questions about the use of the serum cholesterol end point “the CONTAM panel now considers the uncertainty regarding causality to be larger. This is primarily due to a postulated biological process around the enterohepatic cycling of both PFASs and bile acids, the latter affecting serum cholesterol levels. This should be further investigated.”
- 3.4.5 The EFSA 2020 consultation values have not been included in the table below as the consultation is not complete. Exposure to 0.1 µg/L in drinking water would also exceed the TWI of 0.008 µg/kg bw proposed by EFSA in its draft consultation which is equivalent to 0.00116 µg/kg bw from 2020. This was based a no observed adverse effect concentration (NOAEC) for the sum of PFOA, perfluorononanoic acid (PFNA), perfluorohexanesulphonic acid (PFHxS) and PFOS, in a study on vaccination response in one year olds. PBPK modelling was used to extrapolate the NOAEC to a maternal daily intake of 1.16 ng/kg bw per day for the sum of PFOA, PFNA, PFHxS and PFOS. An intake of 3.3 ng/kg bw is about 3 times higher than this EFSA intake. COT noted that breastfed infants in the UK could be receiving levels above the EFSA TWI. However, these are environmental contaminants that cannot be removed from the diet. A reduction in antibody response would have serious health consequences, but it is not known what the threshold is for this effect and there does not appear to be any evidence in the general population that vaccine efficacy is being impaired in the UK.

Country/body	TDI or similar reference point	Adult daily intake of 3.3ng/kg-bw as a % of reference point	Infant daily intake of 10ng/kg-bw as a % of reference point
US	20 ng/kg-bw	17%	50%
Australia	20 ng/kg-bw	17%	50%
Canada	60ng/kg-bw	5.5%	17%
EFSA 2018	1.8 ng/kg-bw	183%	555%

Action advised

- 3.4.5. The Tier 3 level is the concentration above which drinking water may be unwholesome and water companies should therefore 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 0.1 µg/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 0.1 µg/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 2020 (PFOS concentrations above 1.0µg/l)

- 3.5.1. Under the provisions of the Water Industry (Suppliers' Information Direction) 2020 ('the Direction'), water companies are required to notify the Inspectorate of any event which, because of its effect or likely effect on the quality or sufficiency of water supplied by the supplier gives rise, or is likely to give rise, to a significant risk to the health of persons to whom the water is supplied.
- 3.5.2. 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. Given the uncertainty in the toxicological evaluation described above and the recognition chemicals can accumulate in the body and may have short term effects the Inspectorate advocates a precautionary approach. The Inspectorate's view is that companies should initiate their notification arrangements under the Information Direction at PFOS concentrations above 1.0 µg/L.

Derivation

- 3.5.4. The Inspectorate's view is that notwithstanding 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 > 1.0µg/l. This value is derived from the tier 3 (wholesomeness) level established in the previous edition of this guidance.

Action advised

- 3.5.5. Where water companies detect PFOS concentrations in excess of 1.0µg/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 0.1 µg/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 2016 and the Water Supply (Water Quality) Regulations 2018 (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.

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 tiered 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. This clearly places the responsibility on the individual water companies to assess the risks at all treatment works.

4.2.2. Companies should include a consideration of whether levels of PFOA constitute a potential danger to human health or are likely to be unwholesome in their risk assessment. As most of the uses of PFOA are now prohibited, companies will have to use local knowledge to understand the historic uses in the catchments they abstract from. This knowledge can be supplemented by and refined in light of the companies' own raw water monitoring, data from the Environment Agency and, in respect of surface water, data gathered under the industry's collaborative Chemical Investigation Programme (CIP). Companies may need to undertake monitoring in order to adequately assess risks of PFOA, especially where multiple hazards exist.

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

Action advised

4.2.4. 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 0.01 µg/L)

Derivation

4.3.1. In determining guidance on Regulation 10 (Sampling: further provisions) the Inspectorate's approach for PFOA is to mirror the pragmatic approach taken for PFOS. A threshold of 0.01 µg/L is proposed as a level that can be reliably and accurately measured using modern analytical techniques.

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

4.3.3. This trigger is well below toxicological based standards established in the US, Canada and Australia that are considered to pose no significant risk to health from long-term exposure.

Action advised

4.3.4. Where water companies detect levels of PFOA in treated drinking water supplies above 0.01 µg/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 0.1 µg/L)

4.4.1. Regulation 4 prescribes standards of wholesomeness in respect of water supplied by water companies that is intended for human consumption including for such domestic purposes as include cooking, drinking, food preparation and washing or for food production purposes. Regulation 4(2) requires (*inter alia*) that, in order to be regarded as “wholesome”, water must not contain any substance at a level which would constitute a potential danger to human health³. When considering “potential danger to human health” it is important to consider chemicals in relation to lifetime exposure.

Derivation

4.4.2. The February 2018 proposal, from the EU Commission, to revise the Drinking Water Directive included a proposed standard for any individual PFAS of 0.1 µg/L and 0.5 µg/L for total PFAS. These values are more stringent than the recommendation made by the World Health Organisation (WHO) to the Commission of 4.0 µg/L for PFOA. The Commission likened the values in the proposal to the pesticide standard and noted that whilst above US and Swedish value were described as feasible to meet.

4.4.3 The final text of the Directive, agreed by European Parliament’s Committee on Environment, Public Health and Food Safety (ENVI) on the 18 February 2020 and the European Council at the Environment Council on 5 March 2020, includes an even more stringent standard of 0.1 µg/L for the sum of 20 named PFAS and retains 0.5µg/L for total PFAS.

4.4.3. In order to establish guidance on the interpretation of Regulation 4(2) with respect of a concentration which may be a potential danger to human health, the Inspectorate has taken into consideration the recent toxicological reviews described above, and the acknowledged uncertainties in estimates of exposure to PFOA from other sources and the present knowledge of levels in water.

4.4.4. The Inspectorate considers that it is reasonably practicable to consider concentrations of PFOA in drinking water up to 100 ng/l as meeting the wholesomeness requirements of Regulation 4(2). This value is well below the WHO advice to the Commission though above the USEPA health advisory. 100 ng/L corresponds to a daily in take of 3.3ng/kg bw for a 60 kg adult drinking 2L per day and 10ng/kg bw for a 10kg child drinking 1 L per day. These intakes generally

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”

correspond to only a fraction of TDI that have been established by authoritative bodies (see table below). The exception is the PTDI proposed by EFSA in 2018 derived using a physiologically based pharmacokinetic (PBPK) model from the BMDL for a 5% increase in serum cholesterol. The 2020 EFSA consultation raised questions about the use of the serum cholesterol end point “the CONTAM panel now considers the uncertainty regarding causality to be larger. This is primarily due to a postulated biological process around the enterohepatic cycling of both PFASs and bile acids, the latter affecting serum cholesterol levels. This should be further investigated.”

4.4.5 The EFSA 2020 consultation values have not been included in the table below as the consultation is not complete. Exposure to 0.1 µg/L in drinking water would also exceed the TWI of 0.008 µg/kg bw proposed by EFSA in its draft consultation which is equivalent to 0.00116 µg/kg bw from 2020. This was based a no observed adverse effect concentration (NOAEC) for the sum of PFOA, PFNA, PFHxS and PFOS, in a study on vaccination response in one year olds. PBPK modelling was used to extrapolate the NOAEC to a maternal daily intake of 1.16 ng/kg bw per day for the sum of PFOA, PFNA, PFHxS and PFOS. An intake of 3.3 ng/kg bw is about 3 times higher than this EFSA intake. COT noted that breastfed infants in the UK could be receiving levels above the EFSA TWI. However, these are environmental contaminants that cannot be removed from the diet. A reduction in antibody response would have serious health consequences, but it is not known what the threshold is for this effect and there does not appear to be any evidence in the general population that vaccine efficacy is being impaired in the UK.

Country/body	TDI or similar reference point	Adult daily intake of 3.3ng/kg-bw as a % of reference point	Infant daily intake of 10ng/kg-bw as a % of reference point
US	20 ng/kg-bw	17%	50%
Australia	160 ng/kg-bw	2%	6%
Canada	19 ng/kg-bw	17%	53%
EFSA 2018	0.8 ng/kg-bw	412%	1250%

Action advised

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 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 0.1 µg/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 100 ng/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 2020 (PFOA concentrations above 1 µg/l)

- 4.5.1. Under the provisions of the Water Industry (Suppliers' Information Direction) 2020 ('the Direction'), water companies are required to notify the Inspectorate of any event which, because of its effect or likely effect on the quality or sufficiency of water supplied by the supplier, gives rise, or is likely to give rise, to a significant risk to the health of persons to whom the water is supplied.
- 4.5.2. 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 PFOA concentration that would require more immediate intervention (and notification of relevant stakeholders).
- 4.5.3. Given the uncertainty in the toxicological evaluation described above and the recognition chemicals can accumulate in the body and may have short term effects the Inspectorate advocates a precautionary approach. The Inspectorate's view is that companies should initiate their notification arrangements under the Information Direction at PFOA concentrations above 1.0 µg/L.

Derivation

- 4.5.4. The Inspectorate's view is that notwithstanding 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 > 1.0µg/l. This value is derived from the tier 3 (wholesomeness) level established in the previous edition of this guidance for PFOS and advice from PHE that PFOA and PFOS should be treated similarly.

Action required

- 4.5.5. Where water companies detect PFOA concentrations in excess of 1 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 1.0µg/l as soon as practicable.

Water unfit for human consumption

- 4.5.6. As with all notifications received under the Information Direction 2020, 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 20016 (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.

5. Other perfluorinated chemicals

- 5.1. PFOS and PFOA form part of a large group of over 3000 per and polyfluorinated chemical substances (PFAS). DWI commissioned research to look at the likelihood of individual PFAS substances exceeding 0.1 µg/L. At present there is relatively little UK data for the occurrence other PFAS substances. What is available is summarised along with European data in the report. Based on occurrence data and modelling for selected PFAS the main conclusion was that the probability of individual PFAS exceeding 0.1 µg/L in treated water was low. The full report can be found at : <https://www.dwi.gov.uk/research/completed-research/risk-assessment-chemical/poly-and-perfluorinated-alkyl-substances-in-drinking-water/> .
- 5.2 Some other PFAS have been included in the various authoritative reviews considered above. The EFSA 2020 consultation included 27 PFAS and many were shown to be readily absorbed through the gastrointestinal tract in mammals, including humans. In humans, the estimated half-lives for short-chain PFASs (such as PFBA, PFBS and PFHxA) were found to range from a few days to approximately one month, whereas for compounds having a long perfluoroalkyl chain length (such as PFOA, PFNA, PFDA, PFHxS or PFOS), it can be several years. The EFSA proposed a TWI applied to the sum of PFOA, PFNA, PFOS and PFHxS.
- 5.3 Similarly the Australian guidelines included PFHxS and the guidance value applies to the sum of the PFOS and PFHxS.
- 5.4 Analytical methods will often detect more than one PFAS, for example the standard USEPA EPA method 537.1 for PFAS covers some 18 substances including C6 to C14 alkanic acid and C4, C6 and C8 sulphonic acids.
- 5.2 If companies detect PFAS other than PFOA and PFOS, the Inspectorate would expect water companies to adopt a precautionary approach as these compounds are likely to have similar persistent, bioaccumulative and toxic properties. Companies should notify DWI of any unusual results.

6. On-going work on perfluorinated chemicals

6.1 *Human Biomonitoring for PFAS*

Human biomonitoring (HBM) enable us to determine exposure of the public to environmental chemicals. Public Health England (PHE) have prioritised PFASs as one of the groups of substances which will be included in a human biomonitoring study in England. This study is in the planning stage and results will not be available before 2023. The data will allow the estimation of total exposure from the diet and drinking water. Part of this programme of work will support the FSA evaluation, includes method development, and links with the work being carried out by the Environment Agency

6.2 *Environmental sources of PFOS & PFOA*

The Environment Agency continues to carry out sampling of environmental ground and surface waters to further understand the occurrence of PFOS, PFOA and a wider range of PFAS in the water environment. It also plans method development to

include a wider range of PFAS in its suite and further analysis to determine which of the numerous PFAS substances are most likely to reach water.

6.3. *Drinking water research on PFOS & PFOA*

DWI is in the process of commissioning further work on method development for a wide range of PFAS substances, such that all the 20 substances in the “sum of PFAS” parameter in the latest version of the proposed Directive.

Drinking Water Inspectorate December 2020

Glossary

BMDL10 - the benchmark dose level corresponding to a 10% response

BMDL05 - the benchmark dose level corresponding to a 5% response

COT – The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

CONTAM Panel

EFSA - European Food Safety Authority

HED - Human Equivalent Dose

NOEL No Observed Effect Level

NOAEC No Observed Adverse Effect Concentration

NOAEL No Observed Adverse Effect Level

POD Point of departure

PBT Persistent Bioaccumulative and Toxic

SVHC - Substance of very high concern

UF – uncertainty factor

WHO - World Health Organisation