REVIEW OF NATIONAL ARRANGEMENTS FOR THE SETTING OF HEALTH RELATED STANDARDS FOR CHEMICAL PARAMETERS

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Review of national arrangements for the setting of health related standards for chemical parameters

Final Report

May 1999

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This report details the approaches to risk assessment and standard setting in Denmark, France, Germany, the Netherlands and Italy in relation to chemical parameters in drinking water. The different national arrangements are then compared with the UK approach. The main findings of the review are summarised below and in Table 1.

For substances which have a safe threshold below which there is no risk, all five Member States in principle use, or would use, the same approach to appraisal of toxicological data as that used by the World Health Organisation (WHO), although there are minor national variations.

In relation to genotoxic carcinogens, the accepted level of risk that would generally be used in Denmark and the Netherlands is 10^{-6} and thereby the same as that used for the majority of substances for which this approach was used in the Directive 98/83. It should be noted that in the Netherlands flexibility in relation to the level of risk would be allowed in relation to cost and technical difficulty. In Germany, the acceptable risk approach has until now not been used. Germany has instead taken the approach to potential carcinogens that their presence should be reduced as much as possible and therefore in principle not accepted any level of risk. However, when implementing the new Directive it is expected that those EU standards which are based on the acceptable risk approach will be implemented without change.

In Denmark, Italy, the Netherlands and to some extent also in Germany the policy has been to set more stringent standards than those given in the 1980 Directive if technically feasible. This may also be the case in France through contractual arrangements.

The competent authority is the ministry related to the environment in Denmark and the Netherlands, a combination of the ministry related to the environment and the Ministry of Health in France, and the Ministry of Health in Germany and Italy.

All the Member States use expert bodies to advise in the process of setting drinking water standards. These bodies generally have representatives from health authorities, environmental authorities, and institutions with an interest in the health effects of drinking water. The water supply companies have direct involvement in Denmark and France and provide expertise in Germany. In addition, industry is represented in Denmark, France and Germany, and research institutions and universities are represented in Germany, Italy and the Netherlands.

Table 1 summarises the different national arrangements and allows them to be compared with the UK approach.

Table 1 Summary of Policy Approaches

Policy feature	Denmark	France	Germany	Netherlands	Italy	UK
Competent authority	Environmental Protection Agency	Ministry of Environment and Ministry of Health	Federal Ministry for Environment	Ministry of Housing, Spatial Planning and Environment	Ministry of Health	DETR (formerly DoE)
Additional standards for health related chemical parameters	None	Aldrin Dieldrin Heptachlor, Heptachlor epoxide	1,1,1-Trichloroethane Trichloroethene Tetrachloroethene Dichloromethane Tetrachloromethane	None	None	Benzo 3,4 pyrene Tetrachloromethane Trichloroethene Tetrachloroethene Trihalomethanes
More stringent standards for health related chemical parameters	None	None	Arsenic Lead Barium Boron Sulphate	Sodium Barium	Other organochlorines	Barium Boron
WHO Guidelines followed	Same approach	Yes	Same approach except for some potential carcinogens	Yes	Yes	Same approach except for some potential carcinogens
Acceptable excess lifetime cancer risk	10^{-6}	No information	Acceptable risk approach is not used.	10^{-6}, some flexibility	No information	10^{-5}, subject to medical advice
Influence of cost and technical difficulty on setting standards	More stringent standards if technically feasible	More stringent standards set in contracts for water works if technically feasible	Minimising exposure to potential carcinogens as much as technically feasible	More stringent standards if technically feasible	More stringent standards if technically feasible with current technology	Health based, subject to practicability
Consultation with experts	Yes	Yes	Yes	Yes	Yes	Yes
Consultation with public	No	No	Being considered	No	No	Yes

1 INTRODUCTION

1.1 Background

The Department of the Environment, Transport and the Regions (DETR) commissioned CES in August 1998 to undertake a review of national arrangements in place in a number of EU Member States for setting health related standards for chemical parameters in drinking water. The project was managed on behalf of DETR by the Drinking Water Inspectorate (DWI) and this report details the outcome of the review.

The review covers the approaches to risk assessment and standard setting in Denmark, France, Germany, the Netherlands and Italy in relation to chemical parameters in drinking water. The various national arrangements are discussed in Section 2 of this report, which also contains a summary comparison of drinking water quality standards for chemical parameters. A critical appraisal of these national arrangements is then given in Section 3 of this report and they are compared with the UK approach in Section 4.

1.2 Objectives

The principal objectives of the study were as follows:

- to review the approaches to risk assessment and standard setting in Denmark, France, Germany, the Netherlands and Italy for chemical parameters in drinking water; and

- to compare and contrast these to the approaches adopted by the UK and World Health Organisation (WHO) to recommend guideline values.

The review attempted to establish the following:

- philosophy underlying each approach;
- theoretical underpinning;
- assumptions made;
- methods of calculation; and
- extent to which standards are guided by WHO recommendations.

In identifying the approaches to setting standards, the approaches used in relation to chemicals believed to be carcinogens were distinguished from those where toxicity is thought to be different in nature. Where standards differ from those given in the 1980 EC Directive, an attempt was made to obtain information on the following:

- how toxicology is determined;
- basis for assessing total contribution to diet;
- methods for allocating contribution of drinking water;
- methods used to move from toxicological data to a standard;
- safety factors;
- assessing risk and establishing acceptable level of risk;
- public participation and expert advice; and
- extent to which compliance cost and practical difficulties influence decisions.

A critical assessment was then undertaken of the benefits and weaknesses of each national approach to standard setting. The assessment was supplemented wherever possible by the views of those operating within the system. The extent to which each of the Member States sees a need to set national standards that go beyond obligations under European Law was also explored.

1.3 Legislation and Guidelines

The national standards have been compared with the drinking water quality standards given in the following EC Directives:

- 80/778/EEC *Directive relating to the quality of water intended for human consumption,* OJ L229 30/8/80 (the 1980 Directive, or Directive 80/778); and
- 98/83/EC *Directive on the quality of water intended for human consumption,* OJ L330 5/12/98 (the 1998 Directive, or Directive 98/83).

In addition, comparisons are made with the guidelines published by the World Health Organisation (WHO) *Guidelines for Drinking-water Quality.* The first edition of WHO Guidelines was published in 1984 and the second edition was published in 1993.

1.4 Methods for Deriving Health Based Standards

The WHO (1993) describes two principal approaches to setting health related standards for chemical parameters in drinking water. In considering chemicals for which an estimate can be made of a threshold dose below which toxic effects do not occur, the WHO approach is generally based on calculating a Tolerable Daily Intake (TDI), which includes that from drinking water, relating to the threshold dose. This is widely referred to as the *threshold approach* or *concept.*

The use of this threshold approach may be inappropriate for setting drinking water quality standards for potential carcinogens. If the initiating event in the process of chemical carcinogenesis is the induction of a mutation in DNA, then such a genotoxic mechanism theoretically does not have a threshold and there is a probability of harm at any level of exposure. In these circumstances WHO considers the TDI approach to be inappropriate and a risk extrapolation *model* is applied, which calculates an *excess lifetime cancer risk.* For carcinogens where there is evidence to suggest a non-genotoxic mechanism, ie there is a safe threshold dose, threshold approach may be applied.

The basic principles of these two methods are briefly outlined below. The TDI approach has achieved widespread acceptance, but the *excess lifetime cancer risk,* or *acceptable risk approach* is less widely accepted. Even where the latter method is accepted, there is debate about what should be considered an acceptable level of risk.

1.4.1 *Threshold Approach*

The TDI is normally expressed on a body weight basis (mg/kg or μg/kg) and it represents the amount of material that can be ingested, inhaled and absorbed daily over a lifetime without appreciable risk to health. The TDI is generally derived using toxicity data from human and/or animal studies. The toxicity data are generally used to derive a No Observed Adverse Effect Level (NOAEL) or a Lowest Observed Adverse Effect Level (LOAEL). The NOAEL is defined as the highest dose or concentration of a chemical in a single study, found by experiment or observation, that causes no detectable adverse health effect. If a NOAEL is not available, a LOAEL may be used. Both are usually expressed in mg/kg or μg/kg body weight. The uncertainty introduced by factors such as interspecies variation, intraspecies variation, the adequacy of studies and the severity of the effect, can be taken into account by the use of

Uncertainty Factors (UF). The TDI per kg body weight can then be derived as follows:

$$TDI = \frac{\text{NOAEL (or LOAEL)}}{\text{UF}}$$

In the derivation of the WHO guidelines (1993), the uncertainty factors were determined by consensus amongst a panel of experts using the following approach:

Source of uncertainty	*Factor*
Interspecies variation (animals to humans)	1-10
Intraspecies variation (individual variations)	1-10
Adequacy of studies or database	1-10
Nature and severity of effect	1-10

If the uncertainty factor is greater than 1,000, the WHO (1993) designates guideline values as provisional, and it indicates that the uncertainty should not exceed 10,000 or the resulting TDI would be so imprecise as to lack meaning.

A health-related standard for drinking water can then be derived by allocating a proportion (P) of the TDI to drinking water, estimating the daily consumption of drinking water (C), and considering the body weight (BW) of the "at risk" group. The standard can then be calculated as follows:

$$\text{Drinking water quality standard} = \frac{TDI \times BW \times P}{C}$$

The parameters BW, P and C in the above equation can be varied depending on the chemical and the at risk group.

1.4.2 *Excess Lifetime Cancer Risk Approach*

For compounds considered to be genotoxic carcinogens, the WHO guidelines were generally determined using a linearized multistage model and presented as the concentration in drinking water associated with an estimated excess lifetime cancer risk of 10^{-5} (one additional cancer case per 100,000 of the population ingesting drinking water containing the specific substance at the given concentration over period of 70 years). The WHO (1993) emphasises that the guideline values calculated using mathematical models must be considered at best as a rough estimate of cancer risk. It is also noted that the models used are conservative and probably err on the side of caution.

The methods used in risk models attempt to predict the number of test animals which would respond at low exposure levels, based upon observed responses at high dose levels. The multistage model gives a simplistic mathematical description of the rate of cell mutation, cell division and cell death. The linearized multistage model used by the WHO then assumes that the carcinogenic process can be approximated by a series of multiplicative linear functions. The dose response predicted by this model is approximately linear at low doses and is consistent with the "no threshold" approach to carcinogenesis. Using dose response data from carcinogenicity studies, the model calculates a carcinogenicity potency factor for humans, q_1^*. A drinking water quality standard can then be calculated using the following formula:

$$\text{Drinking water quality standard} = \frac{(10^{-x})\ BW}{(q_1^*)\ C}$$

where 10^{-x} is the risk level (x=4, 5 or 6, generally).

There is conjecture about what is an acceptable level of risk. The European Commission's Scientific Advisory Committee to Examine the Toxicity and Ecotoxicity of Chemical Compounds (CSTE), in its opinion on the revision of the Drinking Water Directive, generally recommended that the excess lifetime cancer risk used should be 10^{-6}, ie a factor of 10 more stringent than that generally used by the WHO in determining its guideline values. In evidence to the House of Lords Select Committee (1996), Professor Anthony Dayan, a leading toxicologist involved with CSTE and many other international committees on health related aspects of drinking water quality, stated that determining risk factors "*is partly a matter of public perception and partly a matter of .... democratic and political belief.*" He indicated that "*there has been a growing practice in the past 10 or 15 years to believe that a risk of cancer of one in a million over a lifetime is a figure so small as to be negligible. That has really come to the toxicologist from engineers*". In practice, some of the parametric values for potential carcinogens given in Directive 98/83 are based on a risk factor of 10^{-6}, whilst most of the others are based on less stringent levels, generally because of limitations imposed by analytical detection or technical feasibility. The exception is the new EU standard for benzo(a)pyrene of 0.01 μg/l. When compared with the 1993 WHO guideline value of 0.7 μg/l for an excess cancer lifetime risk of 10^{-5}, the EU standard is set at a risk level of 1.4×10^{-7}, ie more stringent than 10^{-6}.

1.5 Chemicals for Which Health Related Standards Have Been Set

In undertaking the comparison of national arrangements, the scope has not been limited to those chemical parameters for which the EC and WHO standards have been set on a health related basis. Enquiries were made about any chemical parameter for which the national standard was different to that given in Directive 80/778, in order to establish whether the particular national standard had been set on a health related or other basis. For the sake of completeness, the results of these enquiries are detailed in this report, even when it was found that the standard had not been set for the purposes of health protection. It should be noted that the quality and level of detail in the discussion also reflects the difficulty, or otherwise, in obtaining information from each of the Member States approached.

2 NATIONAL ARRANGEMENTS

2.1 Denmark

2.1.1 *Legislation and Guidance*

The Danish legislation and key guidance concerning the quality of drinking water is as follows:

- *Regulation concerning water quality and inspection of water supply systems, No. 515, 1988*
- *Guideline on health related assessment of chemical substances in drinking water, No 1, 1990*
- *Guideline concerning certain compounds in drinking water, May 1984*

2.1.2 *National Standards*

It should be noted that approximately 99% of Danish drinking water is produced from high quality groundwater, which is aerated and sand filtered prior to distribution. Disinfection is only used on water from groundwater sources in the rare event of microbial contamination in the distribution system. The Danish Water Supply Statistics (1996) indicate that in general only surface water is disinfected. Surface water accounts for only about 1% of supply and is generally only used during the summer months.

Denmark has adopted the majority of the EU standards. For a few parameters, where the quality of Danish raw water is better than the standards given in Directive 80/778, Danish standards are more stringent than EU standards. The more stringent standards were set to ensure that pollution does not "fill the gap" between the natural concentrations and the EU standards. This policy also helps secure as good a water quality as possible. The specific parameters for which Denmark has more stringent standards are summarised in Table 2.1.1 and discussed below.

Table 2.1.1 Differences Between Danish Standards and Directive 80/778

Chemical parameter	**Guide Value (GV)**		**Maximum Admissible Concentration (MAC)**	
	Denmark	**EU**	**Denmark**	**EU**
Surfactants reacting with methylene blue	"not detectable"		100 μg/l	200 μg/l
Phosphorus (as P_2O_5)	"not detectable"	400 μg/l	344 μg/l (as P_2O_5, 150 μg/l as P)	5000 μg/l
Potassium	None given	10 mg/l	10 mg/l	12 mg/l

Surfactants

For surfactants reacting with methylene blue, the 1980 EU Maximum Admissible Concentration (MAC) is 200 μg/l, whereas the Danish value is 100 μg/l. This was set in recognition of the limitations of the methylene blue analysis method, which only detects anionic detergents. Non-ionic surfactants, which are not detected by the methylene blue method, constituted about half of the detergents used in Denmark at the time the standard was set. Lowering the value to half the EU MAC was therefore designed to take into account the presence of non-ionic surfactants and limit the total surfactant concentrations to approximately 200 μg/l. It should be noted that the standard set for surfactants is to prevent either foaming or taste and odour problems in drinking water. It is not generally considered a health related standard and the more stringent Danish standard was not set on a health related basis.

Phosphorus

The EU Guide Level (GL) for phosphorus (as P_2O_5) is 400 μg/l and the MAC is 5000 μg/l, whereas the Danish GL level is "not detectable" and the MAC is 344 μg/l as P_2O_5 (150 μg/l as P). It is understood that the more stringent Danish values were originally set to assist in minimising the discharge of the nutrient phosphorus, from domestic wastewater, into the environment. In water resources and where low phosphorus content limits bacterial growth in the distribution system, the addition of phosphorus may induce bacterial growth. The quality of the majority of Danish supplies is such that disinfection is not usually required and the standard was set in attempt to maintain this situation.

The standard is therefore interesting because it relates to the protection of both environmental quality and drinking water quality. It does not however relate to the protection of health from any toxic properties of phosphorus or its compounds, rather to reducing the risk of microbiological contamination. The basis for the MAC being set at a value of 344 $\mu g/l$ as P_2O_5 is not entirely clear, but it is understood to have been set on the basis of achievability.

Potassium

The EU GL for potassium is 10 mg/l and the MAC is 12 mg/l, while in the Danish regulations there is only a MAC value of 10 mg/l. The Danish EPA considered that the basis for setting the EU MAC at such a precise value as 12 mg/l was not justifiable on health grounds (it is understood that it was proposed on the basis of dividing a proposed standard for sodium by a factor of 10). The Danish MAC was therefore set at a "round figure", which was less than the MAC given in Directive 80/778, ie 10 mg/l. Again, this variation from the 1980 Directive does not relate to a standard set for health related reasons.

From the discussion given above it is clear that the majority of Danish drinking water standards which are incorporated into national legislation are the same as those given in the 1980 Directive. The only variations were not determined on the basis of health related assessments. It is interesting that the phosphorus standard was set to assist in controlling environmental quality. It is not known whether such an environmental protection approach will be carried forward into the revision of the Danish standards which will occur in relation to the 1998 Directive. However, it was noted that since the standard for phosphorus in drinking water was set, many more urban wastewater treatment plants in Denmark have incorporated phosphorus removal, so it may not be considered so important to control phosphorus in drinking water.

2.1.3 *Approach to Setting Standards*

The toxicological basis that would be used for the setting of any non-legislative Danish drinking water standards is described in *Guideline on health-related assessment of chemical substances in drinking water (1990)*. This guideline was prepared for the evaluation of substances not included in the drinking water regulations, and was issued by the Danish EPA to inform the local authorities of the principles of toxicological evaluation and help them in their evaluation of the drinking water monitoring results, particularly in the case of contamination by chemicals not given in existing national legislation. It was not used specifically to set the drinking water standards in the current Danish legislation. The methodologies given in the guideline are briefly described below.

Threshold Approach

The determination of standards for substances which can be assessed by the threshold approach, is based on toxicological studies, such as animal studies, studies of specific effects, and epidemiological studies. In the guideline a distinction is made between compounds for which a no effect level can be observed (NOEL = No Observable Effect Level), as is the case for nitrate, and compounds where a NOEL cannot be observed, as is the case for genotoxic compounds (see below).

For each compound, a Tolerable Daily Intake (TDI) is calculated. In the case where a NOEL exists, a set of safety factors is used in the calculation of the TDI to account for the uncertainties of the extrapolation from animal to humans (SF1 = 10), to protect vulnerable parts of the population (SF2 = 10) and to compensate for poor quality of the toxicological data (SF3 between 1 and 100, generally about 10). Decisions on safety factors are made by experts within the Ministry of Food, Agriculture and Fisheries.

The contribution from drinking water to the TDI is assessed individually for each compound based on knowledge of its occurrence in food, air and the environment. No general method for the determination of the contribution of drinking water to the TDI has been published. In general, it is assumed that 10% of the TDI is contributed by drinking water, but this would be determined on a case by case basis.

The standard is calculated by dividing the TDI contributed by drinking water by the daily consumption of drinking water. This is generally determined using a consumption of 0.03 l/day/kg body weight for adults (approximately 2 l per 70kg adult), or 0.25 l/day/kg body weight for babies. If the at risk group is "hard labouring adults" a consumption of between 4 l and 6 l would be used.

Excess Lifetime Cancer Risk Approach

In the case of the genotoxic compounds, a risk-based approach is used to calculate the TDI. A generally accepted lifetime risk is 10^{-6}, as suggested by the CSTE for several of the parameters in Directive 98/83. The TDI is calculated by the One-hit model, developed by the US EPA and described in the Danish EPA report *Industrial Air Pollution Control Guidelines* (1992). It is a mathematical model from which a tolerable concentration of a compound in water can be determined. It includes factors such as human body weight, tolerable lifetime risk, lifetime of the animals used in experiments, daily doses, time of exposure incidents of tumours and daily intake of drinking water (usually 2 litres). The One hit model is based on the biological theory that a single "hit" of some minimum critical quantity of a carcinogen at the target DNA can initiate an irreversible series of events which eventually lead to a tumour.

The One hit model has been criticised for being too strict and for providing uncertain results when the input data are of poor quality.

An addition model is used for assessing the combined effect of the presence of several compounds in the drinking water. Synergistic and antagonistic effects are not taken into account.

These methods broadly reflect the methodological approach used in deriving the 1993 WHO guidelines. The acceptable level of risk in relation to genotoxic parameters is an order of magnitude lower (10^{-6} cf 10^{-5}). As noted above, the approaches outlined above have not been used specifically for setting drinking water standards which are incorporated into legislation. They are guidelines, mainly intended for use during contamination incidents.

2.1.4 *The Decision-making Process*

The following organisations are participants in the decision-making process for setting drinking water quality standards.

Competent Authorities

The government department with responsibility for policy with respect to drinking water quality is the Ministry of Environment and Energy, Danish EPA, 3rd Department, Office of Water Supply.

Experts

The Danish standards for drinking water quality are set by the Danish EPA. In the process of setting the standards, the Danish EPA has appointed and consulted an advisory group of interested parties such as the Health Authorities, the National Association of Local Authorities in Denmark, Danish Industry, the Danish Water Works Association, Copenhagen Water Supply, etc. The Danish EPA considers that the involvement of this group helps ensure that the standards are widely accepted prior to publication of the regulations, and the problems of non compliance are minimised.

Specialist expertise in the toxicological evaluation of chemical substances is provided by the Institute of Food Safety and Toxicology of the Ministry of Food, Agriculture and Fisheries. A member of the Institute has a seat on the EU Scientific Advisory Committee for Toxicology, Ecotoxicology and Environment (CSTE). The Institute assists the Danish EPA if it is necessary to consider the health effects for substances found in drinking water but which are not considered in EU legislation, for example in the case of contamination of supply with a chemical not listed in EU Directives.

Water Companies

The Danish water supply industry is decentralised. In 1996 there were 356 municipal water suppliers providing 63% of the water and 2,768 private suppliers providing 37%. In addition 100,000 buildings were provided with water from private wells. The largest of the water companies is the Copenhagen Water Supply (CWS). It is part of the Municipality of Copenhagen and is one of the organisations specifically consulted by the Ministry in setting drinking water standards in Denmark.

It is the opinion of Janne Forslund of the EPA that the Danish standards for drinking water quality are widely accepted by Danish society as well as by the political parties. There is generally good agreement between public and political opinion on the standards set by the administration.

2.1.5 Adoption of the 1998 Directive

A formal decision on the adoption of the 1998 Directive had not been made at the time that this report was prepared. However, it is understood from sources close to the competent authorities that it is likely to adopt the Directive without amendment.

2.2 France

2.2.1 Legislation

The Decret which implements the Drinking Water Directive, and also other directives relating to the quality of water is: *89-3 relatif aux eaux destinees a la consommation humaine a l'exclusion des* *eaux minerales naturelles (4 janvier 1989).*

2.2.2 *National Standards*

The standards set out in Decret 89-3 implement the Directive. The only addition to Directive 80/778 is for pesticides. In addition to the 0.1 μg/l overall standard there are national standards for four pesticides, namely aldrin and dieldrin in total, and also heptachlor and heptachlor epoxide in total. In both instances the standard is 0.03 μg/l.

The other values adopted in the Decret are the same as required by the Directive with only minor exceptions being for chloride (200 mg/l against a guide value of 250 mg/l) and copper (1000 mg/l compared with a guide value of up to 3000 mg/l). These differences have not been adopted for health related reasons.

2.2.3 *Approach to Setting Standards*

As can be seen from the discussion above, the general approach is to adopt the European standards without variation. The main exception to this appears to be the additional standards for pesticides. In this case, the 1993 WHO guideline values have been adopted without further analysis, at a national level, of the toxicological data nor of the acceptable level of risk.

2.2.4 *The Decision-making Process*

The following organisations are involved with the decision-making process in relation to drinking water standards.

Competent Authorities

The two government departments with responsibility for drinking water quality are the Ministry of Environment and the Ministry of Health.

Direction l'action sanitaire et sociale (DASS)

In each Department the DASS runs its own laboratory (Laboratoire Publique) which carries out monitoring and analysis of drinking water. These laboratories are independent of the water companies and their role is to report to the government, the European Commission and consumers.

Experts

The Conseil Superieur d'Hygiene Publique de France is a committee which draws together representatives of organisations which have relevant expertise. It includes the health authorities (central and local), the Ministry of Environment, those responsible for safety in buildings and water supplies (three from private companies, a representative of the Paris water supply authority and a representative of the Union of Public Water Suppliers). This committee is chaired jointly by the health and environment ministries.

Water Companies

In France, water is supplied by town authorities (approximately 25%) and by private companies (approximately 75%). However, the water supply companies do not own the water supply assets or plant, but they do operate the plant. Water supply contracts are let to the water companies, where competition is based on numerous criteria including the quality of the water to be supplied. Hence drinking water quality standards which are outside the scope or more stringent than required by the Directive can be enforced through the contract.

One of the terms of the contracts is to use the assets to the best effect. Hence if the plant is capable of supplying water at standards which are better than required by the Decret, then the water supply company is contractually bound to do so.

Regulation of Drinking Water Quality

There are several levels of regulation of drinking water quality and the presence of such a regulatory structure influences the approach to setting national standards which have legal effect.

As discussed above, the Laboratoire Publique are independent monitors of water quality who report to the government, and in particular the Prefecture of each Departement. The Prefect has the power to control the supply of drinking water. In addition, the larger water companies such as Lyonaise des Eaux, General des Eaux and SAUR, carry out their own monitoring and sponsor substantial research programmes.

Also, the drinking water quality standards which apply in any one supply-area might be more stringent than required by the Decret 89-3 owing to contractual agreement between the water supply company and the town authorities.

The monitoring undertaken by the independent and private laboratories is often wider in scope than required by the Decret 89-3. The criteria against which the results are assessed are often practically determined by a consensus of experience of the Laboratoire Publique, the water supply company's scientists and the published and unpublished work of academic researchers.

Standards

The Conseil Superieur d'Hygiene Publique de France advises the government on drinking water quality standards. The scientific input to the process of setting standards is based upon the WHO Guidelines and for that reason, where the WHO Guidelines suggest a lower value than required by the Directive then the WHO standard is generally adopted (see for example the standards for pesticides such as aldrin and dieldrin of 0.03 μg/l).

2.2.5 *Adoption of the 1998 Directive*

It is anticipated that the revised Decret will follow the requirements of the revised Directive in terms of the MAC and scope of parameters.

2.3 Germany

2.3.1 *Legislation*

Drinking water quality standards are given in the Trinkwasserverordnung (Drinking Water Ordinance) 1990, as amended in 1991 and 1998. Responsibility for drafting the Ordinance lies with the Bundesministerium fur Gesundheit (Federal Ministry for Health) and work has recently commenced on drafting a new Ordinance to comply with the 1998 Directive.

2.3.2 *National Standards*

The current drinking water quality standards for health-related chemical parameters generally reflect the standards given in Directive 80/778, with the exception of the differences noted in Table 2.3.1 overleaf.

The background to a number of the standards given in the 1990 Drinking Water Ordinance are given in the *Die Trinkwasserverordnung; Einfuhrung and Erlauterungengen fur Wassersorgungsunterehmen und Uberwachungsbehorden* (The Drinking Water Ordinance; Introduction and Explanation for Water Supply Companies and Regulatory Authorities), the so-called "Blue Book", published in 1991. Key information from the entries for arsenic, lead, barium and boron is discussed after Table 2.3.1

Table 2.3.1 Differences Between German Standards and Directive 80/778

Chemical Parameter	Standard		Notes
	German MAC	80/ 778/EC	
Arsenic	10 $\mu g/l$	50 $\mu g/l$	Health based, using threshold approach, see below.
Lead	40 $\mu g/l$	50 $\mu g/l$	Not strictly health based, see below
Organochlorines 1,1,1 trichloroethane trichloroethene tetrachloroethene dichloromethane in total	10 $\mu g/l$ total	None	Not health-based. Compromise between minimisation of exposure and levels typically found.
tetrachloromethane	3 $\mu g/l$		Believed to be based on tentative WHO guideline of 1984.
Barium	1 mg/l	1 mg/l (G) No MAC	Health-based, see below.
Boron	1 mg/l	1 mg/l (G) No MAC	Based on limiting dose from drinking water relative to food, see below.
Calcium	400 mg/l	No MAC 100 mg/l (G)	Not health based. To protect distribution system.
Chloride	250 mg/l	No MAC 25 mg/l (G)	Not health-based. To protect distribution system from corrosion.
Sulphate	240 mg/l	250 mg/l	Compromise value close to 200 mg/l recommended by German Expert panel on Baby Health to protect the young kidney.

The differences between the German standards and those in Directive 80/778 are discussed below.

Organochlorines

The range of health related chemical substances are the same as those given in Directive 80/778 with the exception of Directive parameter 32 "Other organochlorine compounds not covered by parameter 55" for which the Directive gives no MAC and which is omitted from the Ordinance. However, the Drinking Water Ordinance 1990 includes the following additional MACs in relation to organochlorine compounds:

- 1,1,1 trichloroethane
- trichloroethene
- tetrachloroethene
- dichloromethane in total 10 $\mu g/l$

- tetrachloromethane 3 $\mu g/l$

The Umweltbundesamt (UBA, the Federal Environment Agency) indicated that the German standard for the four organochlorine compounds (1,1,1 trichloroethane, trichloroethene, tetrachloroethene and dichloromethane) in total was not set on a health-related basis using toxicological data. It represents a compromise between minimising exposure and levels typically found in drinking water in Germany and was set with the aim of preventing any further deterioration.

It was initially indicated by UBA that the tetrachloromethane standard was derived in Germany in 1986, based on the concept of a threshold dose below which no adverse effects will occur (threshold approach), not an excess lifetime cancer risk. However, the Blue Book does not give details as to how the standard of 3 $\mu g/l$ was derived. On further enquires, UBA was unable to find documented evidence relating to the standard, but gave anecdotal evidence that it was likely to have been based on the 1984 WHO tentative guideline value. The WHO value is based on an excess lifetime cancer risk of 10^{-5}, and derivation of a standard on this basis is inconsistent with current policy in Germany.

The Blue Book states that the sum of the five compounds listed above should not exceed 10 $\mu g/l$, such that should the concentration of tetrachloromethane be 3 $\mu g/l$, the total concentration of the other four chlorinated hydrocarbons should be limited to 7 $\mu g/l$.

Arsenic

The standard of 10 $\mu g/l$ is based on the threshold concept even though it relates to cancer risk. It uses data from studies of human exposure to arsenic in drinking water in Antofagasta (Chile) and Taiwan. The at risk group is identified as young children of body weight 10 kg. On the basis of the studies, it takes as a NOAEL an intake of 500mg in the first year of life and uses a safety factor of 100 (for small children) to give a total acceptable annual dose of 5mg/child. Assuming drinking water consumption of 1litre per day, this gives a limit value of 13.7 $\mu g/l$, which was rounded down to 10 $\mu g/l$ for adoption as the standard in the 1990 Ordinance. The WHO independently arrived at the same value in 1993, but based on the excess lifetime cancer risk approach with an acceptable risk of 10^{-5}. The WHO has also indicated that a similar value may be derived from the Joint FAO/WHO Expert Committee on Food Additives suggested Provisional Tolerable Weekly Intake (PTWI) of 15 $\mu g/kg$ body weight, established in 1988.

Lead

The standard for lead of 40 $\mu g/l$ was not based on a strictly scientific approach. The Blue Book contains some discussion of the then current concentrations of lead in drinking water in Germany. It notes that the average concentration in "uncontaminated water" is about 9 $\mu g/l$, that levels of 20 $\mu g/l$ are not usually exceeded and that in only three of the "registered cities" are levels approaching 40 $\mu g/l$ generally found.

It states that for most adults the main route of exposure to lead is likely to be from food, unless there is occupational exposure. It notes the Food and Agriculture Organisation (FAO)/WHO PTWI figure of lead in food as 3 mg of lead and equates this to 50 $\mu g/kg$ for a 60 kg adult, or about 1 $\mu g/kg$ of absorbed lead. However, it identifies the most at risk group as small children and notes that their dose is likely to be critically influenced by intake of lead from air and water. The other sensitive at risk group is identified as pregnant women.

Based on a PTWI of 1 $\mu g/kg$ of absorbed lead, it is concluded that, because of the high sensitivity of babies, the concentration in drinking water should be reduced to 2 to 3 $\mu g/l$. Lead free water is therefore recommended for drinking and food preparation for babies. It also notes that because it is unlikely that the intake of lead from food can be reduced, other at risk groups should have the intake of lead from air and drinking water reduced. The paper concludes that the lead in drinking water standard should be "maintained or reduced further".

The paper does not appear to state explicitly the derivation of the standard of 40 $\mu g/l$. However, it would appear that it was based on what is practically achievable in Germany, which was assessed by drinking water quality monitoring to be less than the standard of 50 $\mu g/l$ given in the 1980 EC Directive.

Barium

The barium standard of 1mg/l is based on the threshold approach. The Blue Book cites a LOAEL of 10 mg/l for systolic effects in rats, which is then converted to a NOAEL of 1 mg/l for humans by using a safety factor of 10. A TDI for total barium intake of 20 mg/person/day is cited and it is noted that with a drinking water standard of 1 mg/l (10% allocation to TDI), this leaves a large margin of safety for intake from other sources. It notes that the WHO had indicated that other sources of barium would typically be only 2 mg/day. From this discussion, it would appear that this standard was not derived using a classical threshold approach, but is health based.

Boron

The standard is based on the guide value of 1 mg/l given in the 1980 Directive. The Blue Book contains discussion of a LOAEL in trout embryos and larvae and indicates that the toxicity of boron to the reproductive system had not been fully proven. Based on research that indicated that the daily intake of boron was typically between 10 and 80 mg, it was calculated that at 1 mg/l the intake from drinking water would not exceed more than 20% of the typical daily intake from food. Hence it can be seen that the German MAC for boron was not set on a strictly toxicological approach, but on limiting the dose from drinking water relative to that from food.

The 1990 Ordinance contains consideration of substances permitted for drinking water treatment and includes threshold values after treatment for some residuals and byproducts, including trihalomethanes. The 1990 trihalomethane standard of 10 $\mu g/l$ is more stringent than the MAC given in the 1998 Directive. It is not health-based, but represents minimisation of exposure after considering what is technically achievable by the German water companies.

2.3.3 *Approach to Setting Standards*

From the discussion given above it can be seen that where German standards differ from Directive 80/778, the UBA has generally made its own assessment rather than adopting WHO guidelines. However, they have on occasions independently arrived at the same limit values. The UBA's recommended levels have then been adopted by the Ministry for Health.

Wherever possible the UBA uses human toxicology data, but will use animal data where human data is not available. Standards are set wherever possible using the threshold concept and safety factors in relation to uncertainty. In respect of carcinogens, the UBA does not use the risk extrapolation model used by the WHO. Where appropriate it would use the threshold concept, otherwise the approach is based on minimisation of exposure. It is however likely that the tetrachloromethane standard was adopted from the 1984 WHO guideline value, which was derived using a lifetime excess cancer risk of 10^{-5}. In addition, it is considered likely that the new Ordinance will adopt unchanged the parametric values in the 1998 Directive, some of which have been derived using an excess lifetime cancer risk model.

The basis for the approach of minimising exposure can be traced back to a government edict of 1906, which stated that only those water sources that can supply flawless drinking water should be used. This has been interpreted by UBA as *"free of technically avoidable and unneeded residues and/or contamination."*

Policy on Acceptable Risk

As noted above, where a safe threshold dose cannot be determined, for example for potential carcinogens, the policy is based on minimisation of exposure to what is technically achievable rather than using an acceptable risk approach.

In determining MACs for non-carcinogenic substances, four uncertainty factors are considered, as shown in Table 2.3.2 below.

Table 2.3.2 Uncertainty Factors Used in Germany

Factor	Value or Range	Source of Uncertainty
SF_a	10	Extrapolation from subchronic to chronic effects, if appropriate
SF_b	3-10	To estimate NOAEL from LOAEL, if appropriate
SF_c	10	Interspecies variation
SF_d	3-10	Intraspecies variation

Dieter and Konietzka (1995) give a detailed discussion of the use of these uncertainty factors. If uncertainty factors are greater than 3,000 in total then calculation of a limit value is regarded as unsafe and better data would be required to assess risks on a toxicological basis. The approach of minimising exposure is adopted in this situation.

Where no toxicological data are available, a limit value of 0.1 $\mu g/l$ would be regarded as acceptable.

Data and Models

In the absence of human toxicity data, animal data are used. In calculating a TDI, an uncertainty factor of up to 3,000 regarded by UBA as acceptable. This can be contrasted with the approach of the WHO (1993) which indicates that a total uncertainty factor should not exceed 10,000 and for substances for which uncertainty factors are greater than 1,000, guideline figures are designated as provisional to emphasise the high level of uncertainty inherent in the values.

There is no formal procedure in Germany for determining the contribution of drinking water to diet. A consensus is generally reached between experts within the UBA. Typically this is based on an intake of 2 litres a day by an adult and drinking water making a 10% contribution to the TDI.

2.3.4 *The Decision-making Process*

Competent Authorities

Responsibility for drafting the Ordinance lies with the Bundesministerium fur Gesundheit (Federal Ministry for Health) and work has recently commenced on drafting a new Ordinance to comply with the 1998 Directive.

The new Ordinance will be subject to widespread consultation prior to submission to national parliament. There will be an initial informal consultation stage followed by redrafting and a formal consultation stage. Consultees will include:

- Federal Ministry of the Environment;
- Relevant Ministries in the Lander (Regional States);
- Expert committees;
- Water companies;
- Industry;
- Agriculture;

- Environmental groups; and
- Public

The Ordinance is then subject to scrutiny and comment by Parliamentary committee, redrafted and then submitted to Parliament for debate in both Chambers, amendment and incorporation into federal law.

The Ministry for Health is advised by a number of experts and expert committees. The key expertise in relation to chemical parameters resides in the Institute for Drinking Water, in the Institute for Water, Soil and Air Hygiene, within the Federal Environment Agency (Umweltbundesamt (UBA or FEA)). The Institute also convenes the key expert panel, the Drinking Water Committee, for advising and making recommendations to the Ministry for Health. In the consultation process, the recommendations of this committee are given the greatest weight.

A representative of the Ministry for Health indicated that the UBA is currently considering what methods are to be used in determining any variations to the health-related parameters in the 1998 Directive. He indicated that he regarded this as an area of difficulty and would like to see both a national and international consensus. It was also indicated that new Ordinance is likely to be more closely related to the 1998 Directive than the 1990 Ordinance was to Directive 80/778.

Expert Bodies

As noted above, the key expert body relied on by the Ministry for Health is the Institute of Drinking Water, within the UBA and in particular the recommendations of its expert committee. This consists of about 20 members drawn from the following bodies:

- Federal Ministries;
- Federal Environment Agency;
- Regional States;
- Universities;
- Water Research Institutes; and
- Water Companies.

Members are expected to act as individual experts, not lobbying representatives for their employers.

The Chairman of the UBA's Drinking Water Committee indicated that in making recommendations in relation to drinking water standards to the Ministry for Health, the committee considers mainly health-related matters and to a lesser extent technical achievability. Social acceptability, cost and willingness to pay may also be considered by the Ministry of Health, but in the past this has not been in a particularly transparent manner. Consideration is being given to holding a Public Hearing in relation to the new Ordinance.

The Committee Chairman indicated that in considering health risks they have a philosophy of minimising exposure where technically achievable, which may go beyond the standards given in the Directive. The UBA will work with industry and agriculture to reduce at source emissions of chemicals to water resources. However, they do recognise the limits of technical achievability and, for example, that although a more stringent standard might be desirable for bromate based, on health criteria, this would be limited by achievability.

The Committee's recommendations are published by the Federal Environmental Protection Office. They are not binding on the Ministry of Health. The data and rationale behind the drinking water standards adopted in legislation are published in the *Die Trinkwasserverordnung*, the so-called German "Blue Book".

Water Companies

Water supply is undertaken by a large number of relatively small companies, generally serving municipalities. In 1998 there were approximately 7,000 water supply companies, of which 90% were in public ownership with the balance being private sector ownership.

The most influential trade association in the water industry is the Federal Association of Gas and Water Industries (BGW) which represents 1300 of the largest water supply companies, and which account for approximately 90% of the drinking water supplied. The BGW will make official representations to the Ministry for Health in relation to the implementation of the 1998 Directive and the revised Ordinance. In reaching a common position amongst its members, the BGW will consult internally and also externally. The latter would involve consultation with relevant Federal Ministries (eg Health, Environment, Industry), Ministries in the Lander, industry, political parties and pressure groups. It was indicated that in Germany, the water supply companies generally accept the health-related standards that are set by expert bodies such as the UBA and WHO and restrict their representations to matters of technical achievablity and cost.

2.3.5 *Adoption of 1998 Directive*

As noted above, the UBA believes that the Ministry for Health is likely to wish to adopt wholesale the standards given in the 1998 Directive. The only existing parameter for which a more stringent standard already exists in Germany is trihalomethanes and the UBA considers that the existing standard of 10 $\mu g/l$ is likely to be retained, although it believes the first draft of the Ordinance will suggest 100 $\mu g/l$.

The UBA considers it likely that the bromate standard will initially be set at 10 $\mu g/l$, on the basis of technical achievability. It was noted that there is widespread use of ozone in Germany and the German water companies lobbied for a less stringent standard in the Directive. However, the UBA will in the future be considering a health-based standard for bromate and considers it likely that the Drinking Water Committee may then recommend a more stringent standard, possibly to be phased in over a period of time. Such a recommendation would have to be considered by the Ministry for Health.

2.4 Italy

2.4.1 *Legislation*

Drinking water quality standards are given in the Decree of 24 May, 1988 regarding EEC Directive 778/80, *Decree of the President of Republic 24/05/88, n. 236, in fulfilment of the EEC Directive n. 80/778 concerning drinking water quality, as deriving from Art. 15 of Law 16/04/87, n. 183.* The Decree is published in the Official Gazette p4170 No 236 1998 (DPR 236).

2.4.2 *National Standards*

The current drinking water quality standards for chemical parameters largely reflect those given in Directive 80/778/EEC, with the exceptions shown in the Table 2.4.1. It should be noted that it proved difficult to obtain definitive information on the reasons for the differences between the Italian standards and those given in Directive 80/778. The discussion in the notes in Table 2.4.1 reflects this difficulty.

Table 2.4.1 Differences Between Italian Standards and Directive 80/778

Chemical parameter	GV		MAC		Notes
	Italy	EC	Italy	EC	
Potassium	10 mg/l	10 mg/l	-	12 mg/l	There is no Italian MAC for potassium. The GV is same as 80/778/EC.
Other organochlorines (organohalogens in Italian legislation) not covered in 55	1 μg/l	1 μg/l	30 μg/l	As low as possible	The Italian MAC was to be implemented by May 1991 and covers all organohalogens., not just organochlorines It was fixed on the basis of technical achievability from the typical chlorination processes used in Italy. It is not based on a health related assessment. Although it strictly covers all organohalogens, in practice it is used as the Italian THM standard.
Copper	0.1 mg/l	0.1 mg/l	1 mg/l	None	The Italians have adopted a MAC where none is given by 80/778/EEC. The MAC is more stringent than the taste and discolouration level of 3 mg/l given in 80/778/EEC. The Italian MAC is same as the WHO 1984 GV relating to staining properties. It was set from an assessment of existing concentrations in drinking water and is designed to prevent any deterioration in the future. It is not health based.
Zinc			3 mg/l	None	The Italians have adopted a MAC where none is given by 80/778/EEC. The MAC is more stringent than the 5 mg/l taste threshold given in EEC 778/80. It was set from an assessment of existing concentrations in drinking water and is designed to prevent any deterioration in the future. It is not a health based standard.

There are no additional chemical parameters beyond those given in Directive 80/778.

From the above table it can be seen that those national standards which have been set which are more stringent than the standards given in the 1980 Directive are based either on what is considered technically achievable with existing technology used in Italy, or on the basis that existing concentrations in drinking water are below the EC standards and that by imposing a stricter standard the current position is prevented from deteriorating. None of the Italian national standards have been set solely on a health-related basis.

2.4.3 *Approach to Setting Standards*

It proved difficult to obtain information from the Italian Authorities on their approach to setting standards, but it would appear, from the information gathered, that the EC standards are adopted for the majority of parameters. Where standards are more stringent than the standards given in Directive 80/778, this usually reflects the fact that existing drinking water quality is of a higher standard. The philosophy behind adopting these more stringent standards would appear to be prevent any deterioration in drinking water quality.

It is understood that the Italian policy during the negotiations for the 1998 Directive was generally to support the WHO guideline values.

2.4.4 *The Decision-making Process*

Competent Authorities

The responsibility for setting drinking water quality standards is now vested in a permanent Committee established by the Ministry of Health with Decree 26/03/91 (*Technical rules in application of the Decree of the President of Republic 24/05/88, n. 236, in fulfilment of the EEC Directive n. 80/778 concerning drinking water quality, as deriving from Art. 15 of Law 16/04/87, n. 183*).

The Committee is chaired by the General Director of Public Health Services of Ministry of Health and includes:

- 1 representative from formerly Ministry of Agriculture and Forestry, now Ministry for the Agricultural Policy;
- 1 representative from Ministry of Environment;
- 1 representative from Ministry of Trade and Industry;
- 1 representative from Ministry of Public Works;
- 2 representatives from Ministry of Health;
- 1 representative from Ministry for the Coordination of Community Policy ;
- 1 representative from Ministry for the Coordination of Regional Affairs and

Institutional Problems;

- 5 experts designated from Regional Administrations;
- the Presidents of the Departments of the Superior Council of Health;
- 1 representative from the Water Research Institute of the National Research Council; and
- 2 representatives from Superior Institute of Health.

The Committee is renewed every three years.

Expert Bodies

In considering standards, the committee would rely on material published by WHO, US EPA and recommendations made by the Superior Institute of Health.

Water Companies

The organisation of water supply companies in Italy varies from area to area. There are municipal, district, provincial and regional companies which can be wholly publicly-owned, wholly privately owned or a mixture of private and public ownership. The majority is in public ownership, but the trend is towards privatisation.

All the water supply companies are represented at national level by the trade association Federgasacqua. This body would respond to consultation documents and lobby on behalf of the companies in relation to proposed drinking water quality standards.

2.4.5 *Adoption of 1998 Directive*

It is likely that the standards given in the 1998 Directive will be adopted for the large majority of standards. However, it is likely that the Italian standard for chlorinated organic compounds of 30 $\mu g/l$ will be retained, as this is considered to be technically achievable in Italy.

2.5 The Netherlands

2.5.1 *Legislation*

The government department with responsibility for policy with respect to drinking water quality in the Netherlands is the Ministry of Housing Spatial Planning and the Environment (Directorate of Water Supply, Water and Agriculture). The Ministry has a wide range of responsibilities for the supply of drinking water. These are set out in:

- Water Supply Act (1957) — containing rules for the supervision of the water companies and the reorganisation of the public drinking water supply;

- Water Supply Decree (1960) — containing technical, hygiene, medical and administrative implementation measures concerning the Water Supply Act. The Annexes to the Decree were updated by Decree in 1984 it is these Annexes which contain the drinking water standards.

2.5.2 *National Standards*

The drinking water quality standards in the Netherlands are presented in Appendix 2 and it can be seen that:

- there are no standards for substances in addition to those which are listed in Directive 80/778

- the standards are mandatory and generally based on the MACs given in Directive 80/778, with exceptions of the parameters given in Table 2.5.1.

Table 2.5.1 Differences Between Netherlands Standards and Directive 80/778

Chemical Parameter	Standard		Notes
	Netherlands MAC	80/778/EC	
Chloride	150 mg/l	25 mg/l 200 mg/l (G)	Not health based. Set to minimise "pit" corrosion of pipes.
Sulphates	150 mg/l	250 mg/l	Not health based.
Calcium	150 mg/l	100 mg/l (G)	Not health based
Sodium	120 mg/l (80% ile)	150 mg/l (80% ile)	Health based, see below.
Ammonium	0.16 mg/l N (0.2 mg/l NH_4)	0.5 mg/l NH_4	Not health based. Set on recommendation of water companies to prevent aftergrowth, particularly for supplies which are not subject to disinfection.
Barium	500 μg/l	100 μg/l (G)	Health based, see below.

The basis for the health-based differences are discussed below.

Sodium

The Netherlands National Health Council recommended in 1973 that a the TDI for sodium chloride should be 6g/person/day. This equates to 2.36 g sodium per person per day. An allocation of 10% of this TDI, based on consumption of 2 litres a day, gives a standard for sodium in drinking water of 120 mg/l (rounded figure). It is more stringent than the MAC given in Directive 80/778, which from 1987 gave a MAC of 150 mg/l with a percentile of 80, calculated over a three year period.

For the majority of water sources in the Netherlands, this standard of 120 mg/l would not normally be exceeded. However, some sources, including the Rhine, do show higher sodium levels. The Netherlands legislation allows an exemption from the 120 mg/l standard. The exemption is not to exceed 150 mg/l and based on a series of observations spanning 3 years, during which period at least 80% of the observations must comply with the 120 mg/l limit. Hence even the exemption is more stringent than the MAC given in Directive 80/778.

It was indicated that the next revision of the Netherlands''s drinking water quality standards is likely to include a relaxation of the sodium standard, as there is now an acceptance that the health risks associated with sodium are less than previously assumed.

Barium

The precise derivation of the barium standard is not clearly documented in the minutes of the appropriate meeting held in 1984. There was discussion of epidemiological studies which indicated a NOAEL of 5mg/l. With the application of a safety factor of 10, this would give rise to a standard of 500 µg/l. However, there was also discussion of surface water quality standards and in arriving at its conclusion, the Committee considered the standards for the quality of surface water abstraction given in the Surface Water Directive 75/440/EEC. It was indicated that there was a policy, where practicable, of limiting the drinking water quality standard to approximately twice the most stringent standard given for surface water used for abstraction. The barium standard is 100 µg/l, and a standard of 500 µg/l may have been considered to be the closest practicable value to twice the abstraction value. It is therefore not entirely clear precisely how this standard was arrived at, but it is interesting to note that it may have been derived on the basis of environmental protection, rather than being directly health based.

2.5.3 *Approach to Setting Standards*

Toxicological Data

As discussed above, toxicological data have been used in deriving a few legislative health related drinking water quality standards in the Netherlands, but technical achievability was also considered.

Policy on Acceptable Risks

For hazards which give rise to increased risk of harm to the public, the government applies, as a matter of policy, a standard for excess lifetime cancer risk of 10^{-6}. However, this standard may be amended for reasons of technical difficulty or cost. This approach works in either direction. In simple terms, the policy might be stated as "if it is not too difficult to reduce risk still further, then why not use a lower standard?". Likewise, if a sufficient case is made to show that technical reasons render the standard very difficult to achieve, then a less stringent standard may be accepted.

In the application of drinking water standards, there is a practical approach to dealing with incidents where a standard is exceeded. When a substance is present in concentrations higher than the standard, such that the excess lifetime cancer risk is 10^{-6} to 10^{-5}, it is treated as tolerable in the short term and inspectors work with water suppliers to overcome the problem. At a risk level of 10^{-4}, urgent actions are required.

Data and Models

The data and models that would be used to derive risk-based standards are those used by WHO. The Netherlands participates in WHO programs on drinking water quality and hence the WHO models are supported and used by the Netherlands.

The Governmental Institute for Public Health and Environmental Hygiene (RIVM) undertakes research and gives advice on both water and food quality standards and hence there is consistency in the toxicological data and models used between associated areas of regulation.

Other Policy Matters

There are country-specific factors and principles which inform the decision on certain quality standards:

- in the case where raw water in the Netherlands is generally of better quality than required by the Directive, a standard is used which reflects the principle of maintaining and protecting that good quality water;

- in relation to trans-national catchments, the principle of protecting existing quality is relevant to management and cooperation with neighbouring countries on water quality issues, e.g. the River Rhine;

- the maintenance of existing standards is also supported by the water suppliers, for the reason of maintaining consumer confidence and trust in the water suppliers. To adopt standards which allowed the quality of drinking water to degrade from the *status quo* would have an adverse effect on the perception that the consumers have of the water supply companies;

- parameters in addition to those required by the Directive are avoided because of the risk of subsequent enforcement action by the Commission of the European Communities if the monitoring frequency is not as required by the Directive;

- a benefit which is taken in to account when, and if, setting a more stringent standard than required by the Directive, is the indirect influence in maintaining the quality of the wider environment and in influencing manufacturers to develop their products and processes to have lower environmental impacts and emissions.

2.5.4 *Examples*

Bromate

In order to achieve an excess lifetime cancer risk of 10^{-5}, the WHO (1993) guideline value would be 3 µg/l. However, the problems in reaching this level at water treatment works where ozonation is used for disinfection, were acknowledged and hence a guideline value of 25 µg/l with excess lifetime cancer risk of 7×10^{-5} was set by WHO (1993).

In the Netherlands, the water suppliers and the Ministry are confident that concentrations of less than 5 µg/l are achievable at water treatment works, even where ozone disinfection is undertaken. The bromate standard for works using ozone disinfection is likely to be set at 5 µg/l as a 90 percentile, with a maximum of 10 µg/l not to be exceeded in any circumstances. Where ozone disinfection is not used, a bromate standard of either 0.5 µg/l or 1 µg/l is likely to be adopted.

The principle which is applied to the bromate standard, is that if a lower risk is achievable without significant additional cost, then the lower value should be set as the drinking water quality standard. There is no formal policy to guide the balance between the reduced risk and the additional cost. However, work is currently under way at the Netherlands Waterworks Testing and research Institute (KIWA) to determine a monetary equivalence of disability caused by drinking water.

Chlorinated organic compounds

For chloroform ($CHCl_3$), there has been debate regarding the standard to adopt, where the issue has been the allocation factor for drinking water in the TDI. The WHO (1993) guideline at excess lifetime cancer risk of 10^{-5} is 200 µg/l.

A standard of 25 µg/l was informally proposed by the Ministry, based loosely on the assumption that about 5% of the TDI is allocated to drinking water. However, in the water companies' view, an allocation of 5% of the TDI was unrealistically low and requested a standard of 50 µg/l, corresponding to a higher allocation to drinking water.

2.5.5 *The Decision-making Process*

The following organisations are involved in the decision-making process.

Competent Authorities

The government department with responsibility for policy with respect to drinking water quality in the Netherlands is the Ministry of Housing Spatial Planning and the Environment (Directorate of Water Supply, Water and Agriculture). The Ministry has a wide range of responsibilities for the supply of drinking water.

Water Companies

Water is generally, but not exclusively, supplied by water supply companies which are privately owned. The framework for the supervision and regulation of the water supply companies is set out in the Water Supply Act (1957). This includes the provision of inspectors whose role is to verify compliance with standards set by the Minister.

Experts

The two principal organisations which provide advice on drinking water quality and the setting of standards are RIVM (Governmental Institute for Public Health and Environmental Hygiene) and KIWA (The Netherlands Waterworks Testing and Research Institute). As may be seen from their names, these organisations tend to advise the government and the water suppliers respectively.

The process of analysing the issues and reaching a decision in the Netherlands has centred on a document which was prepared during 1993 and completed in 1994. The report on drinking water quality standards was the result of collaborative work between the participants listed above and chaired by an official of the Ministry. In addition, the committee included three representatives of specialist water quality monitoring and analysis laboratories.

The report was completed at the same time as the start of the negotiations on the revision of the Drinking Water Directive. It is still in use, with some amendment, for the purpose of deciding on the need for additional or more stringent standards than required by the revised Directive. It contains the key principles outlined in Section 2.5.3 above.

2.5.6 Adoption of 1998 Directive

When the relevant laws are amended to take account of the requirements of 1998 Directive, it is likely that a number of standards will be more stringent than required by the directive, including:

- bromate
- trihalomethanes

2.6 Summary

The drinking water quality standards in Member States, the Directives and the WHO Guidelines are summarised in Table 2.6.1

Table 2.6.1 Summary of Drinking Water Quality Standards and Guidelines

Key

MAC - Maximum Admissible Concentration   G - Guide Level   PV-Parametric value   IP - Indicator Parameters for monitoring purposes

Values are MACs (or PVs for 98/83 EC) unless otherwise stated

Parameter	80/778/EEC	98/83/EC	NL	DK	F	D	I	UK	WHO 1993
Chlorides (Cl mg/l)	25 (G) 200 (G)	250 (IP)	150	300	200	250	25 (G)	400 [6]	
Sulphates (SO_4 mg/l)	250	250 (IP)	150	250	250	240	250	250	
Calcium (Ca mg/l)	100 (G)		150			400	100 (G)	250 [6]	
Magnesium (Mg mg/l)	50		50	50	50	50	50	50	
Sodium (Na mg/l)	175 150	200 (IP)	120 [5]	175	150	150	150	150 [7]	
Potassium (K mg/l)	12		12	10	12	12	10 (G)	12	
Aluminium (Al mg/l)	0.2	0.2 (IP)	0.2	0.2	0.2	0.2	0.2	0.2	
Nitrates (NO_3 mg/l)	50	50	50	50	50	50	50	50	50 (G)
Nitrites (NO_2 mg/l)	0.1	0.5	0.1	0.1	0.1	0.1	0.1	0.1	3 (G)
Ammonium (NH_4 mg/l)	0.5	0.5 (IP)	0.2	0.5	0.5	0.5	0.5	0.5	
Kjeldahl Nitrogen(N mg/l)	1		1	1	1	1	1	1	
Mineral oils (µg/l)	10		10	10	10	10	10	10	
Phenols (C_6H_5OH)(µg/l)	0.5		0.5	0.5	0.5	0.5	0.5	0.5	

Parameter	80/778/EEC	98/83/EC	NL	DK	F	D	I	UK	WHO 1993
Boron (B µg/l)	1000 (G)	1000	1000	1000		1000	1000 (G)	2000[6]	300 (G)
Organochlorines (not pesticides) µg/l	1 (G)	10 (TCEs)[1] 100 THMs[2]	1	1		See b) below	30	See c) below	
Surfactants(µg/l lauryl sulphate)	200		200	100	200	200	200	200	
Iron (Fe µg/l)	200	200 (IP)	200	200	200	200	200	200	
Manganese (Mn µg/l)	50	50 (IP)	50	50	50	50	50	50	500 (G)
Copper (Cu µg/l)	100 (G) 3000 (G)	2000	100 3000	3000	1000	3000	100 1000	3000	2000 (G) 1000(complaint)
Zinc (Zn µg/l)	100 (G) 5000 (G)		100 5000	5000	5000	5000	100 3000	5000	
Phosphorus (P_2O_5 µg/l)	5000		4600 [2000 (P)]	344 [150 (P)]	5000	5000 [6700 (as PO_4)]	5000	5000 [2200 (as P)]	
Fluoride (F µg/l)	1500-700	1500	1100	1500	1500-700	1500	1500- 700	1500	1500 (G)
Barium (Ba µg/l)	100 (G)		500	100		1000 MAC	-	1000[6]	700 (G)
Silver (Ag µg/l)	10		10	10	10	10	10	10	
Arsenic (As µg/l)	50	10	50	50	50	10	50	50	10 (G)
Cadmium (Cd µg/l)	5	5	5	5	5	5	5	5	3 (G)
Cyanides (CN µg/l)	50	50	50	50	50	50	50	50	70 (G)
Chromium (Cr µg/l)	50	50	50	50	50	50	50	50	50 (G)
Mercury (Hg µg/l)	1	1	1	1	1	1	1	1	1 (G)
Nickel (Ni µg/l)	50	20	50	50	50	50	50	50	20 (G)
Lead (Pb µg/l)	50	10	50	50	50	40	50	50	10 (G)

Parameter	80/778/EEC	98/83/EC	NL	DK	F	D	I	UK	WHO 1993
Antimony (Sb µg/l)	10	5	10	10	10	10	10	10	5 (G)
Selenium (Se µg/l)	10	10	10	10	10	10	10	10	10 (G)
Pesticides and related products - substances considered separately (µg/l)	0.1	0.1	0.1	0.1	0.1 See a) below	0.1	0.1	0.1	
- total (µg/l)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
PAH (µg/l)	0.2[(3)]	0.1[(4)]	0.2	0.2	0.2	0.2	0.2	0.2, see d) below	

Notes

a) France has MACs of 0.03 µg/l for aldrin, dieldrin, heptachlor and heptachlor epoxide.

b) Germany also has MACs for Organochlorine compounds of 10 µg/l for the total of 1,1,1-trichloroethane, trichloroethene, tetrachloroethene and dichloromethane. MAC for tetrachloromethane is 0.003 µg/l.

c) UK has adopted MACs as follows: tetrachloromethane 3 µg/l, trichloroethene 30 µg/l and tetrachloroethene 10 µg/l. In addition THM standard of 100 µg/l, for aggregate of trichloromethane, dichlorobromomethane, dibromochloromethane and trichloromethane, averaged over 3 months.

d) UK has adopted standard of 0.01 µg/l for benzo 3,4 pyrene, averaged over 12 months

1) Sum of tetrachloroethene and tetrachloroethene concentrations

2) Trihalomethanes - total, as specified in Note 10 of 98/83/EC

3) Sum of 6 PAHs

4) Sum of 4 PAHs, also separate parametric value of 0.01 µg/l for benzo 3,4 pyrene

5) See Section 2.5

6) Averaged over 12 months

7) 80 percentile over 3 years

3 APPRAISAL OF NATIONAL ARRANGEMENTS

3.1 Introduction

Present legislation in all five of the Member States is based on the Directive 80/778. The following information is based on present legislation and can therefore not include any definite information on the approach to be adopted when implementing the new directive. Where information is available (France, Germany and the Netherlands) there are indications that the member states plan to implement the 1998 Directive without changes or additions except in the case where the existing legislation is more stringent than the new Directive. Therefore the information available related to the implementation of the Directive 80/778 is likely also to be applicable when the 1998 Directive is implemented.

3.2 Policy Approaches

The policy approach adopted by the five member states is summarised in Table 3.2.1. Special circumstances in each Member State which have an impact on the policy adopted are discussed below.

3.2.1 Denmark

The water supply in Denmark is mostly based on high quality groundwater. Because of the high quality of water, disinfection is rarely applied. This is the main reason for adoption of more stringent MAC values in a few cases, both because it is possible from a technical point of view and also because it is desirable to maintain the high bacteriological quality of the drinking water without disinfection. It is understood that the phosphorus drinking water quality standard was set in part to protect the quality of surface waters.

The Danish Authorities have published guidelines for assessing health related chemical substances in drinking water, for use in relation to contamination incidents. For carcinogenic substances, this is based on an excess lifetime cancer risk approach, but uses the One hit model rather than the linear multistage model generally used by the WHO . The acceptable level of risk that would be used is 10^{-6}.

3.2.2 *France*

The French system of drinking water supply is mainly based on publicly-owned drinking water facilities operated by private companies. The regulation of drinking water quality is based first on national legislation and secondly on stipulations in the contracts between water companies and local authorities who own the drinking water facilities. The stipulations in the contract may be more stringent than the legislation in cases where the quality of the water resource and the drinking water treatment facility makes it technically feasible to obtain a better drinking water quality.

The present French standards for drinking water correspond to Directive 80/778 for the majority of parameters, the only significant exception being a specification of individual standards for four organochlorine pesticides (aldrin, dieldrin, heptachlor and heptachlor epoxide). For these the WHO guideline values have been adopted without change.

3.2.3 *Germany*

Present legislation in Germany in some cases gives more stringent standards than the Directive 80/778. Where the German standards differ from those of the Directive, it is in most cases based on health consideration. In those cases German authorities have made their own assessment of the toxicological evidence to arrive at a standard.

A significant difference lies in the assessment for those substances where a safe threshold cannot be determined (*i.e.* potential carcinogens). For this type of substance the German policy differs from the acceptable risk approach adopted by WHO and the EC. Instead the policy has been based on minimising exposure as much as technically achievable. However, for the implementation of the 1998 Directive this approach is only expected to be used in cases where existing German standards are more stringent than those of the new directive. Standards in the 1998 Directive which have been derived on the basis of the excess lifetime cancer risk approach are likely to be adopted without alteration.

3.2.4 *Italy*

The Italians have adopted a few standards which are more stringent than those given in the 1980 Directive. These are based either on what is considered technically achievable in Italy with existing treatment technologies, or on the basis of maintaining existing drinking water quality.

None has been derived from health based risk assessments.

3.2.5 The Netherlands

The drinking water standards in the Netherlands correspond to the Directive 80/778 with few changes. The current sodium standard is based on a toxicological assessment made using the threshold approach. In addition, it is understood that in setting standards, consideration has in the past been given to the protection of surface water in relation to future drinking water supply. It is possible that the barium standard may have been set on this basis.

It was indicated that the excess lifetime cancer risk approach adopted by the WHO is supported by the Netherlands authorities, although the general policy on the acceptable level of risk is 10^{-6}. This acceptable level of risk may be amended for reasons of technical difficulty and cost.

3.3 Detailed Comparisons

The approaches to setting standards are compared below.

3.3.1 Appraisal of Toxicological Data and Use of the WHO Guidelines

For substances which have a safe threshold below which there is no risk, all five Member States in principle use, or would use, the same approach to appraisal of toxicological data as that used by WHO. France has adopted WHO guideline values directly whereas Germany makes its own assessment but using the same principles. However, when implementing the 1998 Directive in Germany it is expected that all standards will initially be implemented without a new national toxicological assessment. Denmark has prepared guidelines for undertaking risk assessments for chemicals which are not covered in national legislation and these guidelines use the same principles as the WHO . It has not however set any national legislative standards using these guidelines.

There are some national variations in relation to the uncertainty factors that would be used in determining TDIs from NOAELs, but it has proved difficult to obtain information on firm policies. For some of the countries, this may be because such policies are not explicitly documented. It was indicated that for France, Italy and the Netherlands, the methods used by the WHO to set standards were endorsed, and therefore it might be assumed that the WHO approach to uncertainty factors is also endorsed. Denmark has adopted standard uncertainty factors in relation to extrapolating data from animals to humans and to protect vulnerable parts of the population (UF = 10 in both instances), but retains flexibility in relation to the quality of the toxicological data. Germany has set an uncertainty limit of 3,000, beyond which a TDI would be considered unsafe and the approach of minimising exposure would then be adopted.

3.3.2 *The Acceptable Level of Risk for Potential Carcinogens*

The accepted level of risk for potential carcinogens in Denmark and the Netherlands is 10^{-6} and thereby the same as that used for the majority of substances for which this approach was used in the Directive 98/83. It should be noted that in the Netherlands flexibility in relation to the level of risk would be allowed in relation to cost and technical difficulty. In Germany, the acceptable risk approach has until now not been used. Germany has instead taken the approach to potential carcinogens that their presence should be reduced as much as possible and therefore in principle not accepted any level of risk. However, when implementing the new Directive it is expected that those EU standards which are based on the acceptable risk approach will be implemented without change.

3.3.3 *The Assessment of Costs and Benefits*

In Denmark, Italy, the Netherlands and to some extent also in Germany the policy has been to set more stringent standards than those given in the 1980 Directive if technically feasible. This may also be the case in France through contractual arrangements. The rationale has been a combination of a wish to provide the best drinking water quality possible and a wish to preserve present good drinking water quality by leaving no room for filling the "gap" between present quality and the standard. In principle such an approach includes an estimate of the cost involved but the process for estimating cost has not generally been transparent.

No Member State has until now attempted to make a quantitative estimate of the benefit from setting standards. At present work is ongoing in the Netherlands to determine a monetary equivalence of disability caused by drinking water.

3.3.4 *Decision-making*

The competent authority is the ministry related to the environment in Denmark and the Netherlands, a combination of the ministry related to the environment and the Ministry of Health in France, and the Ministry of Health in Germany and Italy.

All Member States use expert bodies to advise in the process of setting drinking water standards. These bodies generally have representatives from health authorities, environmental authorities, and institutions with an interest in the health effects of drinking water. The water supply companies have direct involvement in Denmark and France and provide expertise in Germany. In addition, industry is represented in Denmark, France and Germany, and research institutions and universities are represented in Germany, Italy and the Netherlands.

At present the public has no direct influence on setting standards for drinking water quality in any Member State. However, in Germany consideration is being given to holding public hearings before implementing the 1998 Directive in German legislation.

3.4 Strengths and Weaknesses

The main difference in the approaches adopted by the Member States relate to the following:

- determination of drinking water standards for potential carcinogens; and
- whether more stringent standards are set for technological reasons.

These two issues are considered below.

3.4.1 *Determining Standards for Potential Carcinogens*

German Approach

Germany has until now not generally used an acceptable risk approach when setting standards for potential carcinogens. The approach has instead been to reduce the presence of such substances to as low a level as is practically possible.

The main strength of the "German approach" is that the risk is minimised and that it provides a clear signal: potential carcinogens are unacceptable in drinking water. It does not rely on a mathematical model, the basis of which may not be accepted by all parties with an interest in drinking water quality. In addition, it does not require any of the parties in the decision making process to determine an acceptable level of risk, which is another area where there is likely to be disagreement between interested parties.

The main weakness of the approach is that it may in some cases be argued that the cost of minimising exposure does not outweigh the benefits. There is no mechanism for attempting to assess what reduction in cancer risk is achieved by minimising exposure, rather than defining a drinking water quality standard based on a more scientific approach. It could be argued in some cases that major expense could be incurred with little or no real reduction in risk. It should be noted that no Member State to date has attempted setting a monetary value on the benefit of setting a standard.

The Excess Cancer Lifetime Risk Approach

The main strength of the acceptable risk approach is that the process of arriving at a standard is transparent, has a scientific basis and the actual risk of a certain standard is estimated. However, although it is generally accepted that models such as the linearized multistage model used by the WHO and the One hit model used by the Danish EPA are conservative in their approach, it is widely accepted that there are uncertainties in the use of these mathematical models. Critics would argue that they over-simplify a very complex process which itself is not fully understood. WRc (1993) indicates that since the mechanism of cancer initiation is not well understood, there is no evidence to suggest that one model may predict risk more accurately than another. The WHO (1993) indicates that "*guideline values for carcinogenic compounds computed using mathematical models must be considered at best to be a rough estimate of cancer risk.*" Hence it may be argued that what is widely accepted as the best available scientific approach still has a high level of uncertainty associated with it.

It should however be noted that the acceptable risk approach can derive values that are lower than technically feasible, and in those cases even this approach gives way to standards based on technical feasibility.

The acceptable risk approach has the weakness as opposed to "the German approach" that standards may be set at a level which could be lower without any material cost, thus leaving room for deteriorating drinking water quality and higher risk than necessary. It also requires a decision to be made about the acceptable level of risk. The WHO has based its guidelines on a risk of 10^{-5}, whilst CSTE and those European countries (Denmark and the Netherlands) for which a defined policy has been identified have adopted 10^{-6} as a general policy. Defining the acceptable level of risk is an area where there may be difficulty in reaching a consensus between all the interested parties.

3.4.2 *Standards Based on Technical Feasibility*

Common drinking water quality standards for a large geographical area have the inherent weakness that the standards will cover areas with widely different qualities of source water and different possibilities for water treatment. Existing drinking water quality may be of a higher standard for certain parameters than the toxicologically safe standard, but there is no direct incentive to maintain existing good water quality. Setting more stringent standards than the EC Directive, when technically feasible, is a means to avoid this issue, and it is employed directly in Denmark, Germany, Italy and the Netherlands and through contractual arrangements in France. The weakness of this approach is that it is not possible to define unambiguously what "technically feasible" means, since the final evaluation of feasibility involves balancing the cost of a certain treatment against the benefit.

When setting standards based on technical feasibility, the decision making process must necessarily include those institutions with technical expertise. Therefore water companies and industry supplying products in contact with drinking water will often be part of expert bodies advising on drinking water standards in countries employing this approach.

4 COMPARISON WITH UK APPROACH

4.1 Legislation

The UK standards for drinking water quality are given in the Water Supply (Water Quality Regulations 1989 (as amended) and these are repeated in the Private Water Supply Regulations 1991. The standards for chemical parameters are reproduced in Table 2.6.1. This section discusses the basis for some of the standards, and also advisory values, and compares this with the approach adopted in the other countries covered in this study.

4.2 Approach to Setting Standards

The 1989 Regulations were drafted by the former Department of the Environment (DoE), in consultation with the Department of Health (DoH). Advice on health related aspects was taken from the Joint Committee on Medical Aspects of Water Quality and the DoH Committee on the Medical Aspects of the Contamination of Air, Soil and Water (CASW). The Regulations were drafted prior to the privatisation of the water utilities and they advised DoE on issues relating to costs and practicalities. The water utilities were not represented on the committees which advised on health aspects. Since privatisation the water industry would provide advice on costs and practicalities through Water UK.

The Fourth Report of the House of Lords Select Committee on the European Communities Drinking Water (1996) includes a Memorandum from the Department of the Environment which contains a statement of the Government's policy on standards as follows:

"The Government considers that standards for the proposed Drinking Water Directive should be set in the light of up-to-date scientific and medical knowledge to provide effective health protection. If standards are not set at the appropriate level this distorts priorities by preempting resources. These resources might better be used either for other aspects of drinking water improvement or on other matters offering greater environmental or health protection benefits.

Standards should also take into account benefits for consumers, and likely costs of achieving them (not only for water consumers but for other industries and activities which may have to bear the costs of achieving the standards prescribed.) The aim should be to achieve an appropriate balance between benefits and costs. Relatively insignificant quality improvements which could be achieved only through *heavy expenditure may well not be justified in the light of other health and environmental benefits which could be achieved with those resources."*

In deriving national standards which differ from those given in EU Directives, the UK policy for substances which can be assessed using the threshold approach, including non-genotoxic carcinogens, would be based on the principles adopted by the WHO. In deriving TDIs from NOAELs or LOAELs, the WHO methodology would be adopted and advice on uncertainty factors would be sought from medical advisors. Toxicological data relating to health effects in humans would be used where this is available. If data from animal studies were to be used, an uncertainty factor of 10 would be applied unless medical advice to the contrary were received. For other uncertainty factors a conservative approach would be adopted, unless medical advice to the contrary were received.

If the at risk group was the adult population, standards would be derived based on a body weight of 70kg and a daily consumption of drinking water of 2 litres. For children and infants, the WHO figures would be used. Where good information is available about the proportion of the daily intake from drinking water, this would be used. The default position would be to allocate 10% of the daily intake to drinking water, with the exception of pesticides which are not herbicides, when 1% is the general default value.

In deriving drinking water quality standards for genotoxic carcinogens, the approach has in the past been to adopt WHO guideline values, derived using an excess lifetime cancer risk of 10^{-5}. However, DETR's medical advisors have reservations about the models used by the WHO. The current policy would be to consider any guidelines published by the WHO, but also to consider how exposure could be reduced as far as reasonably practicable.

4.3 National Standards

The standards in the 1989 Regulations are generally based on the MACs given in Directive 80/778. However, there are a number of standards for additional health based parameters included in the UK Regulations and there are also Maximum Concentrations set for a number of chemical parameters for which Directive 80/778 gives only Guide Levels. These differences are shown in Table 4.1.

Table 4.3.1 Differences Between UK Standards for Health Related Chemical Parameters and Directive 80/778

Parameter	**Standard**			
	UK Maximum Concentration	**80/778 Guide Level**	**80/778 MAC**	**WHO 1984 Guideline**
Boron (μg/l)	2000(1)	1000	NG	NG
Barium (μg/l)	1000(1)	100	NG	NG
Benzo 3,4 pyrene (μg/l)	0.01 (1)	NG	NG (2)	0.01(3)
Tetrachloromethane (μg/l)	3(1)	NG(4)	NG(4)	3 (5)
Trichloroethene (μg/l)	30(1)	NG(4)	NG (4)	30 (5)
Tetrachloroethene (μg/l)	10(1)	NG(4)	NG(4)	10 (5)
Trihalomethanes (6) (μg/l)	100	NG	NG	NG(7)

Notes

NG None Given

1) Subject to Regulation 3(3)d on averaging over 12 months
2) Standard is given for 6 PAHs in total, including benzo 3,4, pyrene
3) WHO standard is given for "benzo(a)pyrene"
4) Guide level of 1 μg/l is given for "*Other organochlorines not covered by parameter No 55*"
5) Tentative guideline value
6) Aggregate of trichloromethane, dichlorobromomethane, dibromochloromethane and tribromomethane, subject to the averaging described in Regulation 3 (3) (e)
7) A guideline value is given for trichloromethane of 30 μg/l

The UK standards for health related chemical parameters which are not specifically included in the 1980 Directive are summarised in Table 4.1 and discussed below.

Benzo 3,4 pyrene

Benzo 3,4 pyrene is included as one of the six PAHs to be included in the aggregated PAH standard given in Directive 80/778 and the UK Regulations. A Maximum Concentration of 0.01 μg/l is also prescribed in the UK Regulations, which is based on the 1984 WHO guideline figure. This guideline value was derived by the application of a linearized, multistage risk assessment model, with an acceptable level of risk set at 10^{-5}.

The UK is the only one of the countries covered by this study to have adopted to date a specific legislative standard for benzo 3,4 pyrene. However, a parametric value of 0.01 $\mu g/l$, based on an acceptable level of risk of 1.4×10^{-7}, ie more stringent than the EU's general policy, is included in Directive 98/83.

Organochlorines, including Trihalomethanes

The UK Regulations do not include a standard for the 1980 Directive parameter 32 *"Other organochlorine compounds not covered by parameter No 55"* (parameter 55 covers pesticides and related products), for which the Directive gives only a Guide Level. The UK adopted instead Maximum Concentrations for the following specific organochlorine compounds:

- tetrachloromethane;
- trichloroethene; and
- tetrachloroethene.

The UK standards in each case were taken from the 1984 WHO tentative guideline values, which for each of the above compounds was derived with a linearized multistage risk assessment model, with an acceptable level of risk set at 10^{-5}.

The German standard for tetrachloromethane is the same as that in the UK and it is understood that it was also derived from the WHO guideline. The German standard for other chlorinated hydrocarbons of 10 $\mu g/l$ in aggregate includes trichloroethene and tetrachloroethene, along with 1,1,1 trichloroethane and dichloromethane. This standard was set on the basis of a compromise between minimisation of exposure and levels typically found in German drinking water. The Italians have set a MAC for *"Other organohalogens not covered by parameter No 55"* of 30 $\mu g/l$, based on technical achievability with the existing technology used in Italy. In practice, this is used as the Italian THM standard.

None of the other countries covered in the study had set legislative standards for specific organohalogens.

The UK standard for trihalomethanes was based on advice from the Joint Committee on the Medical Aspects of Water Quality and consideration of what was technically feasible with the technology used in the UK water industry. It is less stringent than the standard of 10 $\mu g/l$ adopted in Germany on the basis of technical achievability.

Boron and Barium

At the time that the standards for boron and barium were set, it was considered that there was insufficient good quality toxicological data to set a well founded health based standard. The values adopted were based on medical advice and consideration of what was technically practicable.

4.4 Advisory Values for Some Pesticides

The Department of the Environment published guidance and information relating to a number of pesticides in drinking water in the letter WP 18/1989 which is reproduced in Annexe 1 of *Guidance on Safeguarding the Quality of Public Water Supplies* (1989). This contains a table of advisory values for 39 pesticides and WP 18/1989 gives details of how the advisory values were derived.

Three of the advisory values were adopted directly from the then current WHO guideline values (WHO, 1987). Advisory values were set on the basis of the threshold approach described by the WHO (1984). The TDIs were either based on recommendations made by FAO/WHO (1962-1988) or, where no TDI was available from this source, using figures from the Agrochemicals Handbook (1987) and the Pesticide Manual (1987). Standards were set on the basis of a 70 kg adult consuming 2 litres of drinking water per day. A drinking water intake of 10% was allocated for herbicides and 1% for other pesticides, in line with WHO recommendations.

Hexachlorobenzene was the only pesticide considered in the UK guidance for which the WHO (1984) had set a guideline value based on an excess lifetime cancer risk approach. The WHO figure was 0.01 μg/l, based on a level of risk of 10^{-5}. The UK advisory value was set at the less stringent value of 0.2 μg/l. WP 18/1989 states that the "*WHO guideline value, however, was also derived from water quality criteria for rivers, and included an allowance for exposure by eating fish. The higher advisory value of 0.2 μg/l results from removal of this inappropriate allowance.*" Hence the UK value as also based on an acceptable risk of 10^{-5} from drinking water. This is consistent with the acceptable level of risk used to derive the UK organochlorine drinking water standards.

It should be noted that WHO (1993) has since published revised guidelines for a number of pesticides. Where values differ from those given in WP 18/1998, it is generally on the basis of a revised TDI derived from more recent toxicological studies. The difference in the WHO guideline value for DDT (2 μg/l) and the UK advisory value (7 μg/l) is due to the WHO figure being based on the at risk group being a 10 kg child consuming 1 litre of drinking water per day, where the UK advisory value was based on a 70 kg adult consuming 2 litres per day.

4.5 Conclusion

From the above discussion, it can be seen that the UK approach to setting standards which differ from those given in Directive 80/778 has generally been based on the approaches used by the WHO with only minor adaptation.

On the basis of the consultations, the UK approach to substances for which the threshold approach may be applied is broadly the same as that which would be used in Denmark, Germany and the Netherlands, who would all use the WHO approach but retain the flexibility to vary uncertainty factors, the at risk group (and hence body weight and drinking water consumption), and also the allocation of daily intake.

The UK approach in relation to excess lifetime cancer risk has in the past been to adopt WHO guideline values based on an acceptable risk of 10^{-5}. However, DETR's medical advisors have reservations about the models used by the WHO. The current policy would be to consider any guidelines published by the WHO, but also to consider how exposure could be reduced as far as reasonably practicable. France has also in the past adopted unchanged WHO guideline values which were set using an excess lifetime cancer risk of 10^{-5}. This level of risk is an order of magnitude less stringent than the general policy adopted in the 1998 Directive and by the Danish and Netherlands authorities. It should be noted that neither Denmark nor the Netherlands has as yet used an acceptable risk of 10^{-6} to set a unique national statutory drinking water quality standard. Germany does not accept the acceptable risk approach for potential carcinogens and instead seeks to minimise exposure to what is technically achievable.

The policy approaches of all the countries covered in this study are summarised in Table 4.5.1.

Table 4.5.1 Summary of Policy Approaches

Policy feature	Denmark	France	Germany	Netherlands	Italy	UK
Competent authority	Environmental Protection Agency	Ministry of Environment and Ministry of Health	Federal Ministry for Environment	Ministry of Housing, Spatial Planning and Environment	Ministry of Health	DETR (formerly DoE)
Additional standards for health related chemical parameters	None	Aldrin Dieldrin Heptachlor, Heptachlor epoxide	1,1,1-Trichloroethane Trichloroethene Tetrachloroethene Dichloromethane Tetrachloromethane	None	None	Benzo 3,4 pyrene Tetrachloromethane Trichloroethene Tetrachloroethene Trihalomethanes
More stringent standards for health related chemical parameters	None	None	Arsenic Lead Barium Boron Sulphate	Sodium Barium	Other organochlorines	Barium Boron
WHO Guidelines followed	Same approach	Yes	Same approach except for some potential carcinogens	Yes	Yes	Same approach except for some potential carcinogens
Acceptable excess lifetime cancer risk	10^{-6}	No information	Acceptable risk approach is not used.	10^{-6}, some flexibility	No information	10^{-5}, subject to medical advice
Influence of cost and technical difficulty on setting standards	More stringent standards if technically feasible	More stringent standards set in contracts for water works if technically feasible	Minimising exposure to potential carcinogens as much as technically feasible	More stringent standards if technically feasible	More stringent standards if technically feasible with current technology	Health based, subject to practicability
Consultation with experts	Yes	Yes	Yes	Yes	Yes	Yes
Consultation with public	No	No	Being considered	No	No	Yes

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France

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Italy

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