

**OVERVIEW OF NATIONAL AND
INTERNATIONAL GUIDELINES AND
RECOMMENDATIONS ON THE ASSESSMENT
AND APPROVAL OF CHEMICALS USED IN
THE TREATMENT OF DRINKING WATER**

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A report prepared for the National Health and Medical Research Council's
Drinking Water Treatment Chemicals Working Party

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This report has been used by the Drinking Water Treatment Chemicals Working Party to assist in the development of Chapter 8 of the Australian Drinking Water Guidelines – *Assessment and Approval of Drinking Water Treatment Chemicals in Australia*.

This report is not a formal NHMRC position paper, but rather, provides an overview of national and international guidelines and recommendations on the assessment and approval of chemicals used in the treatment of drinking water. Accordingly, the report has not been subject to formal NHMRC public consultation processes.

FOR INFORMATION

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Executive Summary

Australia does not have processes in regulation for the control and use of drinking water treatment chemicals (DWTC). In order to initiate a national approach to assessment and approval of drinking water treatment chemicals in Australia, the National Health and Medical Research Council's (NHMRC) Health Advisory Committee (HAC) established the Drinking Water Treatment Chemicals Working Party (DWTCWP) in 2000. This report, commissioned by the Working Party, describes and compares the policies and procedures used by various national and international organisations and regulatory agencies for:

- Evaluating the public safety of chemicals used to treat drinking water; and
- Approving the use of such chemicals.

In order to manage the quality of water delivered to consumers, most authorities around the world have established 'Guideline Values' for substances that may enter the drinking water supply. For protection of water quality and human health, the quantity of any given substance in water at delivery may not exceed the 'guideline value' for that substance. Unfortunately, the number of compounds on such lists is relatively limited and is too small to enable control of all contaminants that may be in potable water. Therefore, in order to meet their statutory obligations for ensuring the quality and safety of drinking water, many authorities have found it necessary to legislate that the chemicals and materials used by water works be evaluated separately with regard to their toxicology and their possible effect on drinking water quality. With regards to chemicals, such legislation mostly places the statutory onus on the water authority to comply with water quality and safety aspects and they are therefore encouraged to only use evaluated and/or certified products in their processes. Since an evaluation for each chemical product by each individual water authorities would be time consuming and inefficient, and is beyond the resources of most authorities, a variety of central evaluation and control systems have been set up by governments around the world.

Overall it was found that all of the schemes reviewed in this report conducted their evaluations and approval systems on proprietary brands of DWTC rather on generic chemicals. In addition, these schemes conducted public health risk assessments of DWTC with the 'end of pipe' consumer as the target receptor. In most of the approval and assessment procedures there is provision for audits of manufacturing facilities, of manufacturing and management quality systems, of QA/QC systems, and periodical random sampling for chemical analysis of products and raw materials.

The international schemes use two broad processes for the technical assessment of safety. The first is a simple comparison of the chemical constituents, including impurities, of a brand product with a standard for the generic chemical (eg. ferric chloride) that stipulates allowable levels of the constituents/impurities. The standard may also specify the analytical methods that must be used for characterising the proprietary brand of the chemical. Some regulatory bodies have delegated this type of evaluation to non-regulatory, but nonetheless accredited organisations who are also able to issue approval notices for the chemical product being assessed.

The second broad technical assessment process involves a human health risk assessment of the proprietary chemical where, in addition to detailed chemical analysis, varying levels of toxicological information is required. Different methods are used in the risk assessments of

different jurisdictions to calculate the likely concentration of chemical/impurity that may be achieved in the reticulated water supply. This calculated concentration is then compared to a level that is considered to be safe in order to characterise the risks associated with use of the chemical to treat drinking water. With this type of evaluation there is usually significant involvement of the regulatory body issuing the approval notice.

The most highly developed, well-known and transparent evaluation schemes of DWTC are those of the United Kingdom, the United States and the Netherlands.

The United Kingdom has a process whereby an expert committee regularly evaluates and makes recommendations for approval of DWTC on the basis of no adverse effects (health and aesthetics) being likely. Approval is by the designated Authority (the Drinking Water Inspectorate) who publishes a yearly-consolidated list of approved products, and also audits water supply companies for their compliance, amongst other things, regarding use of approved products. Under the UK scheme water companies may use non-approved chemicals if they comply with a European (BS:EN) standard. While a variety of toxicological and non-toxicological information is required by the Committee, written procedures detailing how this information is processed were not available. Application forms and guidance documents are made available to companies and the committee is assisted by a full time secretariat. The scheme is strongly supported by regulations and the evaluation process per se is conducted at no expense to an applicant wishing to have a product approved. Onus is placed on the product manufacturer to notify the authorities of changes in manufacturing process or formulation. The Committee evaluates both materials in contact with potable water and chemicals used in the treatment.

In the US, the individual States are responsible for enforcement of the national water regulations (e.g. the Safe Drinking Water Act) as established by the US EPA. There are two types of standards used to specify requirements for DWTC. The American Water Works Association (AWWA) and the National Sanitation Foundation (NSF) have guidelines that have been incorporated into standards by the American National Standards Institute (ANSI). The ANSI/AWWA standards detail minimum chemical requirements for all traditional generic water treatment chemicals. There is no official certification or approval of products and the onus is on the supplier to demonstrate product conformance with the standard. ANSI/NSF Standards 60 & 61 are health standards which detail minimum requirements and evaluation processes for the control of potential adverse human health effects from use of DWTC and materials in contact with drinking water. Both sets of standards are often used by other countries.

Most US States require DWTC products to be certified to ANSI/NSF, with certification being performed by an accredited organisation, e.g. NSF. The technical process for evaluating a drinking water treatment product according to ANSI/NSF standards is risk based but quite complex. Wherever possible the process utilises existing data. It has a number of pivotal decision points pertaining to the requirement of additional toxicological data on a product. The evaluation process appears to have the flexibility of being technically pragmatic but can bring cutting edge risk assessment methodology into the process if required. In addition to an application fee, the product sponsor pays all costs incurred by the accredited evaluation body. This includes evaluation of the product formulation, conduct of the risk assessment, inspection and accreditation of manufacturing facilities and all chemical analyses performed by the evaluators.

The Netherlands also has a well-developed scheme for evaluating and approving DWTC. The overarching legislation is the EU Drinking Water Directive and the Dutch Drinking Water Decree and Criteria. The Dutch Government in collaboration with the Dutch Water Works Association has established a central evaluation system for materials used in the preparation of drinking water. The Chief Inspector of Public Health has established criteria known as “The Assessment on Toxicological Aspects (ATA)”, against which the evaluation must be made. Kiwa, an accredited third party organisation, administer the regulations and coordinate the health aspects of the chemical product evaluation. The assessment is performed by Kiwa using a combination of chemical standards and committee evaluation of health risks. Kiwa is assisted a sub-committee expert in toxicology whose operation is under the auspices of the Chief Inspector. The overall process makes strong use of a positive list of approved products and allowable levels of impurities, especially for materials. The health risk evaluation process appears to be similar to the committee scheme of the UK, but as with the NSF scheme, the applicant pays all costs associated with the approval of a product.

Introduction / Scope

In 1988, the NHMRC endorsed the “*Guidelines for Clearance of Water Treatment Chemicals and Processes*”. These guidelines outlined the data requirements for drinking water treatment chemicals (DWTC) assessment, and provided a standardised approach to the assessment of their safety and efficacy. However, they were not regulatory requirements and relatively few chemicals were evaluated under the guidelines. Since the mid 1990s there has not been a practical mechanism for the national assessment and approval of DWTC in Australia.

In order to initiate a national approach, in 2000 the NHMRC’s Health Advisory Committee (HAC) established the Drinking Water Treatment Chemicals Working Party (DWTCWP). The primary aim of the DWTCWP is firstly to protect public health and the aesthetic quality of drinking water by ensuring chemicals used to produce potable water are safe and appropriate for the purpose, and secondly to provide the water industry with guidance on drinking water treatment chemicals. The DWTCWP remit is to develop guidelines for the assessment of chemicals used in drinking water treatment processes, to use these guidelines to assess DWTC, and make recommendations to the NHMRC concerning acceptability of chemicals for treating drinking water.

In order to develop these guidelines, the DWTCWP required an understanding and assessment of existing international policies, regulations and guidelines relevant to DWTC. This report details the systematic comparative analysis of existing national and international practices. It summarises the regulatory frameworks under which drinking water treatment chemicals are assessed, and describes and compares the policies and procedures used by various national and international organisations for:

- Evaluating the public safety of chemicals used to treat drinking water; and
- Approving the use of such chemicals.

This report details practices by the following organisations/countries:

- World Health Organization;
- Australia;
- Canada;
- New Zealand;
- United Kingdom;
- American Water Works Association
- United States Environmental Protection Agency;
- National Sanitation Foundation International (USA);
- The Netherlands; and
- South Africa

The report does not make recommendations regarding the suitability of any particular policy or procedure for adoption. In addition, policies and procedures used to judge the technical merits (ie. efficacy) and/or water dosage rates of DWTC’s have not been included in the review.

Materials (e.g. pipes, flanges, seals, surface coatings etc) that come into contact with drinking water are only mentioned in the report in so far as the process for their evaluation compliments or adds understanding/context for the process employed for evaluating DWTC’s. The report therefore concentrates on assessment of drinking water treatment chemicals (DWTC’s).

1. Overview of Schemes for the Evaluation of Chemicals used in the Treatment of Drinking Water

In theory, chemicals and materials used in the production and distribution of drinking water may release a variety of substances into the water. In order to manage the quality of water delivered to consumers, most authorities around the world have established 'Guideline Values' for substances that may enter the water supply¹. For protection of water quality and human health the quantity of any given substance in water at delivery may not exceed the 'guideline value' for that substance. Unfortunately, the number of compounds on such 'guideline' lists is relatively limited and is too small to enable control of all contaminants that may be in potable water. Therefore, in order to meet their statutory obligations for ensuring the quality and safety of drinking water, many authorities have found it necessary to legislate that the chemicals and materials used by water works be evaluated separately with regard to their toxicology and their possible effect on drinking water quality. With regards to chemicals, and other water contaminants such legislation mostly places the statutory onus on the water works for compliance² with water quality and safety mandates and they are therefore encouraged to only use evaluated and/or certified chemical products in their processes. Since an evaluation of all the relevant aspects by each individual water works would be time consuming and inefficient, and is beyond the resources of most facilities, a variety of central evaluation and control systems have been set up by governments around the world. The systems and evaluation processes differ between jurisdictions.

Figures 1.1 and 1.2 present an overview of the basic regulatory foundation and evaluation processes used by countries that have drinking water evaluation schemes in place. In summary, the onus is on the water treatment plant to meet water quality guidelines. They do this by choosing to use chemicals that have been evaluated and listed as 'approved'. Chemical suppliers provide information to evaluators so their chemicals can be included on the 'approved' list (Figure 1.1).

Figure 1.2 shows the two most typical procedures for DWTC evaluation. All schemes reviewed in this report conduct their evaluations and certifications on specific brands of product and not for generic chemicals. Thus, for example, chemical-AA is not evaluated and certified, but brands X, Y or Z of chemical AA receive individual evaluation and/or certification and are placed on an approved list of products'. Diagram A of Figure 1.2 depicts comparison of a branded material to a known and approved standard. The evaluation may be performed by accredited organisations or by the responsible regulatory body. An evaluation of this type usually involves a simple comparison of the chemical constituents (including impurities) of a brand/product with a generic standard that stipulates allowable levels of constituents for the generic chemical in question (eg. alum, ferric chloride etc). Industry finds such standards useful for developing products for drinking water treatment facilities. The generation of an approved standard implies that at sometime a health risk assessment has

¹ These substances (contaminants) may derive from a range of diverse sources not just the chemicals and materials used in the production of potable water.

² The most common form of demonstrating compliance is periodic measurement of water works outflow against all, or judiciously selected parameters in the relevant National Drinking Water Guideline Document.

³ An alternative approval method to a 'listing' is to allow the product to bear a certification logo, which is recognized as indicating the product/brand has been evaluated and approved.

been performed in order to identify allowable impurity levels⁴. A variety of organisations (AWWA, NSF, Kiwa) have such standards.

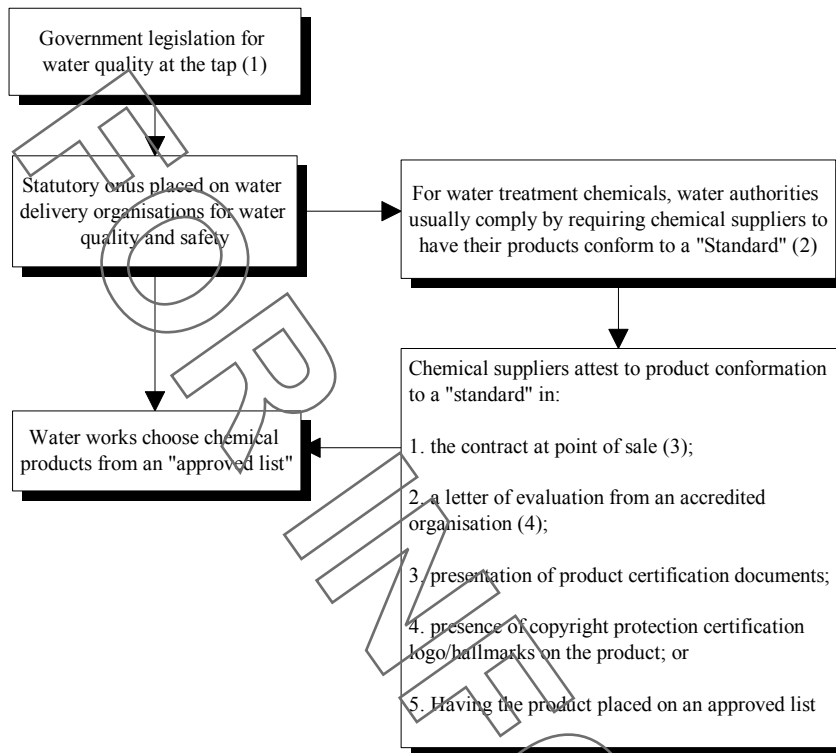
Depending on the jurisdiction, an evaluation may also take the form of a relatively detailed health risk assessment (see Figure 1.2, Diagram B) where toxicological data on the product is submitted and the evaluation proceeds from first principles. Such assessments are usually performed by committees with substantial input/representation from a regulatory agency.

Three well established evaluation schemes for evaluating drinking water chemicals have been examined in detail in this report. These are the procedures of the Committee on Products and Processes for Use in Public Water Supply (UK, Chapter 6), the USA-NSF processes (Chapter 7) and the Kiwa regulations for “Assessment on Toxicological Aspects” (Netherlands, Chapter 8). These three schemes appear to contain the most well developed and sophisticated processes available for the assessment of drinking water chemicals. Table 1.1 summarises and compares the key characteristics of the regulatory environment, general processes and policies of these schemes, whereas Table 1.2 summarises and compares the technical procedures applied for toxicological and safety evaluation of the chemicals for each of the schemes. Summary tables for schemes obtained from other reviewers⁵ of DWTC evaluation processes are presented in Chapter 2.

⁴ Although a chemical constituent standard implies health risk assessments have been conducted in order to establish allowable limits of constituents, Toxikos found no written evidence of formal health risk assessments being performed in the generation of such standards for drinking water chemicals.

⁵ WHO (2000) ‘Guidelines Monograph on the Safety of Materials and Chemicals in the Production and Distribution of Drinking Water’ Draft May (2000).

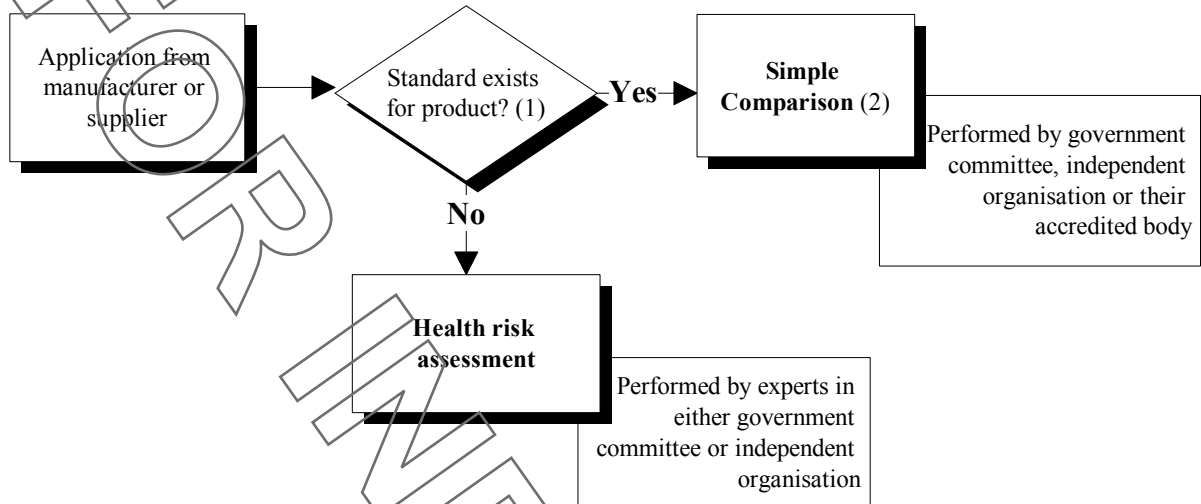
Figure 1.1: Overview of basic regulatory environment underpinning evaluation and certification schemes for materials and chemicals used in the provision of drinking water



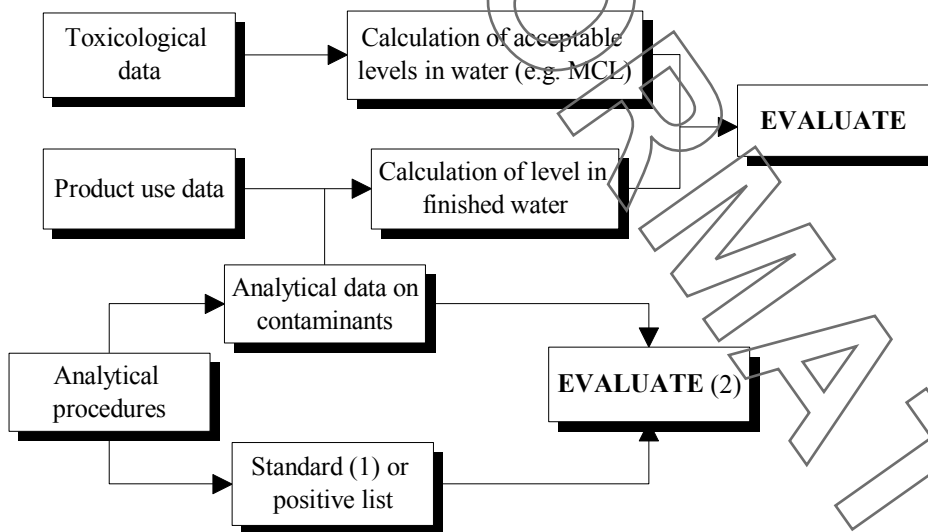
- 1 These are usually broad specifications along the lines that contaminants in drinking water are not allowed to be present in such concentrations that will affect human health or the aesthetic qualities of the water. In addition legislation may specify that other national guidelines shall not be exceeded or that contaminant levels be kept as low as possible even though there is no health risk at higher levels.
- 2 A "standard" may be a generic set of specifications for a particular chemical, or class of chemicals, promulgated by a credible organisation, or may be certification or evaluation by a specific scheme.
- 3 In this circumstance the suppliers 'word' by contract is taken with the water works not necessarily having sighted other forms of proof.
- 4 This may occur where the evaluation has been a health risk assessment from an organisation authorised to conduct those assessments.

Figure 1.2: Overview of the basic technical procedures used for the evaluation of drinking water treatment chemicals

Comparison to a Standard



Health Risk Assessment Technique



¹ This is a standard that specifies particular required parameters of a chemical including allowed levels of impurities. Often the standard also specifies the details of the analytical technique to be used. Standards and positive lists allow efficient, quick evaluation by an authority or independent organisation (or their agents) but also allow the manufacturer to develop products which proactively conform to an approved standard.

² The evaluation in this case is a simple comparison of the analytical results performed on the product against the specifications in the standard.

TABLE 1.1 Summaries of key characteristics of the major international processes for evaluating drinking water treatment chemicals

	USA-NSF	UK	The Netherlands
Governing legislation	US Safe Drinking Water Act and relevant US State regulations/rules.	Regulations 25 to 28 of the Water Supply (Water Quality) Regulations 1989	Drinking Water Decree (DWD) and the Water Works Decree (similar to NHMRC Drinking Water Guidelines) and governing legislation for certification is Kiwa-Regulations for the ATA Product Certificate
Responsible Body	US EPA	'Secretary of State for the Environment, Transport and the Regions' and 'The National Assembly for Wales'. These authorities delegate administration of, and compliance with the regulations to the 'Drinking Water Inspectorate' (DWI).	Chief Inspector of Public Health and Environmental Protection of the Ministry of Housing, Spatial Planning and the Environment (VROM)
Evaluating Organisation	3rd Party Certifying Agency(ies) approved by American National Standards Institute	Committee on Products and Processes for Use in Public Water Supply (CPP)	KIWA (a standards, quality certification organisation linked to VROM).
Cost Recovery	100% (ie. no public money is used in the approval process)	0%, the product supplier does not bear any costs for the approval, but does for the generation of data. The approval process per se is funded with public monies	100% (ie. no public money is used in the approval process). Manufacturer is given a rough quote and interim 'dummy' invoices as evaluation and work proceeds, these are grossed into a final invoice.
Standards/ Guidelines employed	ANSI/NSF2001 Standard 60 – Drinking Water Treatment Chemicals – Health Effects. ANSI/NSF 1998 – Certification Policies for Drinking Water System Components – Health Effects. ANSI/AWWA Standards for Drinking Water Chemicals.	None, the approval processes is by committee but BS: EN Standards (British Standards Institute), CEN Standards (European Standards Institute) are adopted.	Regulations for "Assessment on Toxicological Aspects" (ATA) Positive list provides allowable levels of contaminants in a product (limited for chemicals)
Approved, validated and documented	Analytical techniques, toxicological methods and drinking water standards referenced are	CPP assessment appears to be done by expert deliberation since specific guidance rules for	Kiwa works with VROM in establishing R/A policy

	USA-NSF	UK	The Netherlands
protocols	predominantly derived from approved, and documented US/Canadian Government protocols.	the risk assessment process do not appear to exist. BS: EN standards mandate certain parameters.	
Compliance requirements	Mandatory in the majority of States in USA, voluntary in some and no requirement in a minority of US States	Mandatory on water works in the UK	Mandatory in The Netherlands
Quality assurance / control procedures	Initial evaluation includes review of formulation, laboratory analysis and audit of manufacture. Unannounced audits are carried out once a product is approved. Manufacturers are required to notify the certifying agent of any changes in the manufacturing process	Compliance audits are conducted on the water works to ensure products being used are approved or meet relevant BS:EN Standards	Initial evaluation includes review of formulation, laboratory analysis & audit of manufacture. Regular audits are carried out once a product is approved. Manufacturers are required to notify the certifying agent of changes in the manufacturing process
Toxicology data required	Yes	Yes – extent dependent on product impurities and judgment of CPP. Can direct certain studies be undertaken?	Yes – similar to UK
Toxicology data formally assessed	Yes – by toxicology/risk assessors within NSF, or contracted by NSF.	Yes – by CPP who are an independent group of experts but are not all toxicologists.	Yes, by committee of experts from industry, Kiwa & Authority.
Certification / accreditation	Certification required in most US States	Approval required in the UK	Certification required in The Netherlands
Aesthetic evaluation	No	No	No
Treatment by-products considered	Yes	No information	No information
Efficacy considered	No	No	Yes
Public consultation	No public notification/consultation is required. A listing of approved products is publicly available on the Internet	No public notification/consultation is required. A listing of approved products is publicly available on the Internet	No public notification/consultation is required. A listing of approved products is publicly available.

	USA-NSF	UK	The Netherlands
Approval timeframe	Variable depending on level of evaluation required. Typically 8 to 12 weeks	Variable depending on level of evaluation required. Typically 2-3 meetings of CPP which meets bimonthly.	Variable depending on level of evaluation required. Typically 2-12 months
Approval costs	USD \$3->6K (within continental US)	None	No data
Recognition of foreign approvals	None	Products compliant with EU Standards are recognised with attestation.	No recognition of products approved under foreign schemes
Scheme recognised by foreign countries	Canada (but many countries unofficially recognise the scheme)	None	None

TABLE 1.2: Summaries of toxicology evaluation procedures for drinking water treatment chemicals

	USA ANSI-NSF Standard 60	UK DWI CPP	Dutch KIWA
Required Toxicity Data Set	<p>Threshold of evaluation: concentration of the contaminant is less than 3 µg/L (normalised static system) 0.3 µg/L (normalised flowing system) or 10 µg/l acute conditions then toxicity data are not required</p> <p><10 µg/L genetic toxicity testing >10 - <50 µg/l , genetic, subacute/subchronic toxicity testing 50 µg/L quantitative risk assessment</p> <p>A gene mutation assay such as the bacterial reverse mutation assay with and without exogenous metabolic activation (<i>Salmonella typhimurium</i> or <i>Escherichia coli</i>).</p> <p>An in vitro chromosomal aberration assay. A positive result in either assay necessitates appropriate in vivo genetic toxicity testing.</p> <p>For quantitative risk assessment the minimum dataset includes the genetic toxicity testing required for qualitative risk assessment together with a relevant GLP subchronic toxicity study conducted to OECD, US FDA or US EPA test guideline methods.</p>	<p>All or some of the following may be required depending on the type of chemical and CPP's requirements for risk assessment.</p> <p>Toxicokinetic studies and metabolism data on product components Acute studies, LD50 etc. Dermal toxicity (irritancy & sensitisation) Sub-acute (90 day) Developmental toxicity Carcinogenicity studies Mutagenicity (in vitro & in vivo). Can recommend to DWI research be undertaken.</p>	<p>For both materials and chemicals the toxicity data to be supplied by the applicant is determined after consultation.</p> <p>For materials: the minimum data set for the leached component not on the positive list is; Rat oral LD50 with clinical signs Semi-chronic toxicity study (rat oral 90d, 3 dose groups) Mutagenic potential</p> <p>For chemicals: CGCMD consider that to evaluate the toxicological risk of chemicals applied directly to drinking water "an extensive testing programme like those used for food additives is in principle appropriate". However depending on the application, water dosage level, final calculated concentrations in water and other considerations, the evaluation may take place on a more limited data set.</p>
Toxicology data assessment process	<p>Risk assessment procedures specified in Annex A of the standard are based on US EPA Risk Assessment methodology: a. derivation of RfD (US EPA 1993), benchmark dose (Barnes et. al. 1995), or cancer R/A (US EPA 1996). The RfD is used to derive the total allowable concentration (TAC) in water. The contribution made by drinking water must not exceed 20% of the maximum tolerable daily intake (RfD) for the contaminant.</p> <p>The RfD is calculated by applying an uncertainty factor (UF) of between 10-10000 to the NOAEL/LOAEL/benchmark dose from semi-chronic testing, assuming 70 kg bw, consumption of 2L water per day and 20% allocation of RfD to water.</p>	<p>Expected to be similar to Kiwa or WHO standard assessment procedures.</p>	<p>The general principles employed in data evaluation are those of WHO (1987). The no effect level (NEL) is used to derive the maximum tolerable concentration (MTC) in water. Since intake of the contaminant may come from sources other than drinking water the CGCMD stipulate that the contribution made by drinking water must not exceed 10% of the maximum tolerable daily intake (TDI) for the contaminant.</p> <p>The MTC is calculated by applying a safety factor (SF) of 100 to the NEL from semi-chronic testing, assuming 60 kg bw, consumption of 2L water per day and 10% allocation of TDI to water.</p>

	USA ANSI-NSF Standard 60	UK DWI CPP	Dutch KIWA
	$\text{TAC (mg/l)} = \frac{\text{RfD (mg/kg/d)} \times 70\text{kg}}{\text{UF} \times 2\text{L/d}} = \frac{\text{RfD} \times 35}{\text{UF}}$		$\text{MTC (mg/l)} = \frac{\text{NEL (mg/kg/d)} \times 60\text{kg}}{\text{SF (100)} \times 2\text{L/d}} = \frac{\text{NEL} \times 30}{\text{SF}}$
In use risk assessment	Testing requirements are for both the individual contaminant of a product together with the product	Likely – but details not known.	Likely – but details not known.

2. Recommendations and Initiatives of the World Health Organization

2.1 Background

The 1993 edition of the WHO “Guidelines for Drinking Water Quality” discussed the issue of hazardous chemicals in drinking water derived from treatment chemical products or water supply construction materials. The document concluded that such pollutants in drinking water were best controlled by national regulations governing the quality of the products themselves rather than relying on changes in the quality of the water as a mechanism for alerting to contamination caused by DWTC’s. Unfortunately the background information in the 1993 WHO Guidelines did not contain advice regarding the development of suitable specifications for water treatment chemicals or construction materials, and only a few important drinking water contaminants derived from water treatment chemicals, construction materials, paints and coatings were addressed in the guidelines.

Since the 1993 WHO Guidelines, WHO (2001) has developed a training package to assist countries in developing specifications to ensure that the safety of drinking water is not compromised by water treatment chemicals or construction materials used in delivery systems. The essentials of this package are described in section 2.2.

2.2 Water Treatment Chemicals

For DWTC that contain contaminants/impurities for which there is a national drinking water standard, WHO (2001) advocates the use of the simple dilution equation used by the US National Research Council and National Sanitation Foundation (NSF) to derive a Recommended Maximum Impurity Content (RMIC) in the treatment chemical.

$$\text{RMIC (mg/kg)} = \frac{\text{NS (mg/l)} \times 10^6 \text{ (mg/kg)}}{\text{MD (mg/l)} \times \text{SF}}$$

Where: RMIC = recommended maximum impurity content of a contaminant in the treatment chemical.
NS = the national drinking water standard, or guideline value, used by the national body for the contaminant/impurity in question.
MD = maximum dosage of the water treatment chemical.
 10^6 = conversion factor mg impurity/mg chemical to mg impurity/kg chemical.
SF = safety factor, WHO (2001) consider a factor of 10 is reasonable to limit 10% of a given NS to come from an impurity in a given treatment chemical.

If a national drinking water standard for the chemical impurity, or a suitable guideline from another organisation is not available, WHO (2001) indicates that it may be necessary to conduct toxicity testing on that chemical impurity so a NS ‘value’ can be calculated and then subsequently used to derive the RMIC.⁶

⁶ Note that evaluating bodies such as the US NSF and CPP of the UK, request toxicological data on treatment water chemicals and their impurities at the time a manufacturer submits their product for approval to be used for treatment of water. It is presumed that the WHO (2001) would recommend the principles contained in WHO (1994, 1999) be used, in conjunction with appropriate national science policies, to establish the NS. For Australia these policies are largely articulated in the Australian Drinking Water Guidelines (NHMRC 1996).

2.3 Construction Materials

WHO (2001) recognises that the amount of contaminant released from water supply construction materials into drinking water may initially be high but rapidly declines as the material has continued contact with water. It is suggested that leachate tests, as adopted by the US NSF, can be used to determine the decay curves of contaminants released from construction materials. WHO (2001) states:

“If the initial (day 1) leachate concentration of contaminant is less than or equal to the 90 day NOAEL divided by 100, and the contaminant concentration is calculated to be at or below 10% of the national standard, then no additional toxicity data may be required”.⁷

WHO (2001) suggests the International Organisation for Standardisation (ISO) should be regarded as the appropriate international body for the coordination of national standards and uniform test procedures relating to the extractability of toxic substances from construction materials used to deliver potable water to the public.⁸

2.4 Initiatives

To support countries in developing control procedures for water treatment chemicals and construction materials, the Working Group on Protection and Control of Water Quality of the Rolling Revision of the Guidelines is preparing a monograph (WHO 2000) on the techniques for testing and controlling materials and chemicals. The aim of the monograph is to elaborate on issues related to contamination of drinking water by DWTC and water delivery construction materials and to provide background information that could assist jurisdictions interested in developing their own review and approval systems for such products. A draft monograph has been prepared but it is incomplete and it is unknown when either a publicly available draft or finalised report will be published.

The WHO (2000) draft monograph contains information on evaluation procedures used by European countries and Japan. These have been summarised in table 2.1 so the reader can

⁷ Since leachate concentration is mg/l and NOAEL is mg/kg bw/d, this statement is interpreted as meaning the potential intake of contaminant via drinking water must be less than a health reference toxicity value (in this case 90d NOAEL/100, but could be some other value depending on available data and national policies), and the amount of contaminant in the leachate at the end of 24 hours leaching is below 10% of an existing national drinking water standard (or a facsimile standard as calculated in 2(ii) above). Since the media for the second portion of the statement is not stipulated it is possible to interpret this portion of the statement as meaning, “or the contaminant concentration calculated in the final water at tap”. However Toxikos considers WHO intended the calculated contaminant concentration relates to the day 1 leachate.

$$LC \text{ (mg/l)} \times WI \text{ (l/kg bw/d)} \leq \frac{90\text{d NOAEL (mg/kg bw/d)}}{100} \quad \text{and} \quad LC \leq \frac{NS \text{ (mg/l)}}{10}$$

Where:

- LC = leachate concentration after 1 day.
- WI = daily water intake per kg body weight (e.g. at 2l/person WI = 2 l/70 kg bw).
- NOAEL = no observed adverse effect level identified in a suitable 90 day experimental animal drinking water or food study.
- NS = national drinking water standard for the contaminant(s)/chemical impurities of interest (usually identified by chemical analysis of the leachate using suitable analytical limits of quantification).

⁸ Australia has a national standard (AS/NZS 4020:1999) based on British standard BS 6920, which is used for testing materials for use in contact with drinking water. Standards Australia, in conjunction with the Water Services Association of Australia, has produced guidelines (SAA HB 131-1999) for applying and interpreting AS/NZS 4020. The equivalent ISO standard for plastic pipes is ISO 8795: 1990.

gain an appreciation of the general approaches in place. These schemes are not discussed in detail within the text of this report because of the draft status of the WHO (2000) monograph and because Toxikos was unable to obtain sufficient information on these schemes to allow independent evaluation. Table 2.1 also contains information on schemes for which data was obtained by Toxikos (Australia, Canada, New Zealand and South Africa).

FOR INFORMATION

TABLE 2.1: Summaries of schemes for the assessment of drinking water treatment chemicals and products in contact with drinking water

The table is based on data presented in Chapter 9 of WHO (2000) Guidelines - Monograph on the Safety of Materials and Chemicals in the Production and Distribution of Drinking Water. DRAFT May, (2000) and also data gathered in the preparation of the present report.

	Governing Legislation	Responsible Body	Evaluating Organisation	Standards/Guidelines Employed	Comments
WHO (Draft)	Not Applicable	WHO Working Group on Protection and Control of Water Quality	Not applicable	Guidelines for drinking water quality (GDWQ). Vol. 1 – Recommendations (1993), Vol. 2 - Health criteria (1996), Vol. 3 - Surveillance and control of community water supplies (1997).	
Australia	State Responsibility normally the relevant Health Act	Relevant State Authority normally Department of Health	No formal procedures, ad hoc evaluation does occur	AS 4020 – Products in contact with drinking water does not deal with chemicals	See Chapter 3
Canada	Not reported	Federal Provincial Subcommittee on Drinking Water	3rd Party Certifying organisations, there are currently 3 organisations which are able to certify DWTC's including NSF	Advisory only - ANSI/NSF Standard 60 Drinking Water Treatment Chemicals – Health Effects	See Chapter 4
Japan	None reported	Ministry of Health and Welfare	None however the responsible Ministry promotes collaboration with international certifying bodies	None	
New Zealand	Not reported. The primary code for protecting the safety of drinking water supplies in NZ are the Drinking Water Standards for NZ.	Ministry of Health and regional Councils	None.	The New Zealand Water and Wastewater Association (NZWWA) has produced quality standards for 5 drinking water treatment chemicals.	See Chapter 5

	Governing Legislation	Responsible Body	Evaluating Organisation	Standards/Guidelines Employed	Comments
South Africa	None Personal communication with a water works in RSA indicates there is confidential draft legislation	National Department of Health	No formal procedures, ad hoc evaluation does occur	None currently, procedures are being developed but are at a rudimentary overview stage.	See Chapter 9. An Evaluation Committee will be established which will make recommendations to the Director General of Health based solely on potential health effects of the chemical to domestic water users, and evaluations will be made on the basis of data by an accredited laboratory.
Austria	Austrian law for foodstuffs	Ministry for Health, Sports, and Consumer Protection	OVGW (Osterreichische Vereinigung fur das Gas- und Wasserfach)	Austrian Standard ONORM B 5014/Teil 1.	The Austrian Positive List lists all allowable components. OVGW tests all products in contact with water and Austrian waterworks only recognise approved products.
Belgium	Royal Decrees 25 August 1975, Moniteur Belge No 187, 24/9/1976	None reported	University of Liege and University of Ghent	4 Belgian Standards exist for Products in contact with water, including a positive list. No standards for DWTCs.	Material Products are evaluated for aesthetic and microbiological effects and specific migration testing is carried out. The positive list is based on toxicology evaluation of constituents but no toxicological evaluation of products is required.
Denmark	Not reported	Danish Environmental Protection Agency	ETA-Denmark A/S (certification body) Dansk Standard (certification body)	Approx 9 standards related to plumbing and piping materials used in contact with water. There is no standard for DWTC	Basic testing for aesthetic effects. Microbiological and toxicological testing is not routine but may be required in specific circumstances. Accepts approvals from Nordic countries.

	Governing Legislation	Responsible Body	Evaluating Organisation	Standards/Guidelines Employed	Comments
Finland	National Building Code	Finnish Ministry of the Environment	Finnish Ministry of the Environment	Water supply and drainage installations for buildings, Regulations and Guidelines 1987	Basic testing for aesthetic effects. Microbiological and toxicological testing is not routine but may be required in specific circumstances. Accept approvals from Nordic countries.
France	Article 7 French Regulations on Water Quality (Decret No 89-3 du 3 janvier 1989)	Ministry of Health (expert body, the Council of Public Health)	Compliance bodies CRECP Paris, LHRSP Nancy, and Pasteur Institute Lille.	Circulaire DGSINo94/9	Relevant to products in contact with water only. Includes aesthetic and cytotoxicity evaluation. Recommendations also exist on ion exchange resins and membrane filters.
Germany	No legislation for chemicals but KTW recommendations for products are quasi legal	German Federal Health Office. Working group "Drinking Water Affairs of the Commission for Plastics"	Authorised laboratory (currently 3 in Germany)	KTW Recommendations + DVGW-W 270 German standard for carrying out microbiological testing	Certification is required for products in contact with water, not DWTC's. Aesthetic and microbiological testing is required.
Italy	No specific legislation	Ministry of Health	Manufacturers and suppliers are responsible for compliance	Circular No 102 Health regulations concerning plastic materials and rubbers for pipes and accessories intended to come into contact with drinking water or water rendered fit for drinking.	Products in contact with drinking water
Norway	Norwegian Food Act 1933	Norwegian Food Control Authority	National Institute of Public Health, Folkehelsa (NIPH)	Reference to "Norwegian Standards" is made by WHO (2000) but the standards are not specified.	Products are evaluated for aesthetic effects and specific migration testing is carried out. Toxicity testing is not required as a default.

	Governing Legislation	Responsible Body	Evaluating Organisation	Standards/Guidelines Employed	Comments
Spain	Royal Decree 1138/1990 of 14 September Technical sanitary regulations for the provision and control of quality of water for public consumption	Spanish Ministry for Health and Food	No national approval schemes. Suppliers responsibility. Supplier required to issue a certificate of guarantee that the product complies with the regulations.	Pipes General technical specifications for the health of the population, Order of 15 September 1986. Modification of Royal Decree 211/1992 of 6 March for the approval of a list of permitted substances for the construction of plastic materials and objects in contact with food and regulations concerning the condition of testing.	The approach to plastic products in contact with water is consistent with EU Food contact requirements for food grade plastics.
Sweden	Drinking water ordinance 1993:35 (DWTCs) Planning and Building Act 1987 for products in contact with DW	For DWTCs - National Food Administration Statens Livsmeldelsverk (SLV) For products in contact with DW National Board of Housing Building and Planning	Svenskt Byggodkännande (SHTAC)	Drinking water ordinance 1993:35 includes a positive list of approved treatment chemicals and their purity requirements	
Switzerland	Ordinance on the Treatment of Drinking Water	Federal Office of Public Health	Federal Office of Public Health issues approval certificates for products in contact with DW	Ordinance on the Treatment of Drinking Water	Treatment chemicals are not covered The approach to plastic products in contact with water is consistent with EU Food contact rules

3. The Status in Australia

3.1 Overview

The States and Territories of Australia have the primary responsibility for ensuring the safety of potable water in Australia. At the federal level the NHMRC provides technical and policy guidance for the States and Territories to adopt into their administrative and legislative frameworks if they so wish. Although there are a number of federal chemical registration and control schemes for industrial, agricultural, pharmaceutical and food additive chemicals, there is not a viable equivalent scheme or process for evaluating DWTC in Australia. While it is possible existing schemes could be used for assessing DWTC (see the case study, section 3.3) they are not currently tuned to do so and the resulting process is inefficient.

There are no specific State or Territory legislative requirements for the regulation of drinking water treatment chemicals. An Australian Standard (AS 4020) exists that details requirements for materials in contact with drinking water but this is not intended, nor applicable, for drinking water treatment chemicals. Outlines of current regulatory frameworks and management schemes for drinking water are provided below, together with a case study on a recent approval of a new drinking water treatment resin in Australia.

3.2 Regulatory Background

The primary responsibility for ensuring safe drinking water in Australia is encoded in State and Territory Health/Public Health legislation. In all cases the legislation generically refers to the necessity to provide a safe water supply but there are no State regulatory requirements relating to drinking water treatment chemicals. In most, if not all States and Territories, ensuring a safe water supply involves a cooperative effort between State Health Authorities and the water suppliers. For example, in NSW and Victoria a Memorandum of Understanding (MOU) operates between the various water authorities and the Government (via 'Water Acts' administered by Departments of Health). The essential elements of an MOU are illustrated in figure 3.1. The regulatory process under which the water authorities are responsible for providing potable water to Sydney (i.e. Sydney Water) is outlined here. It should be noted that while many aspects of water quality are considered, there are no specific requirements in the management process pertaining to the selection and/or use of drinking water chemicals. The closest process to proactive management of DWTC quality appears be at the point of sale, where there may be a contractual agreement (see section 3.3) with the chemical supplier regarding the technical requirements of the chemical being supplied.

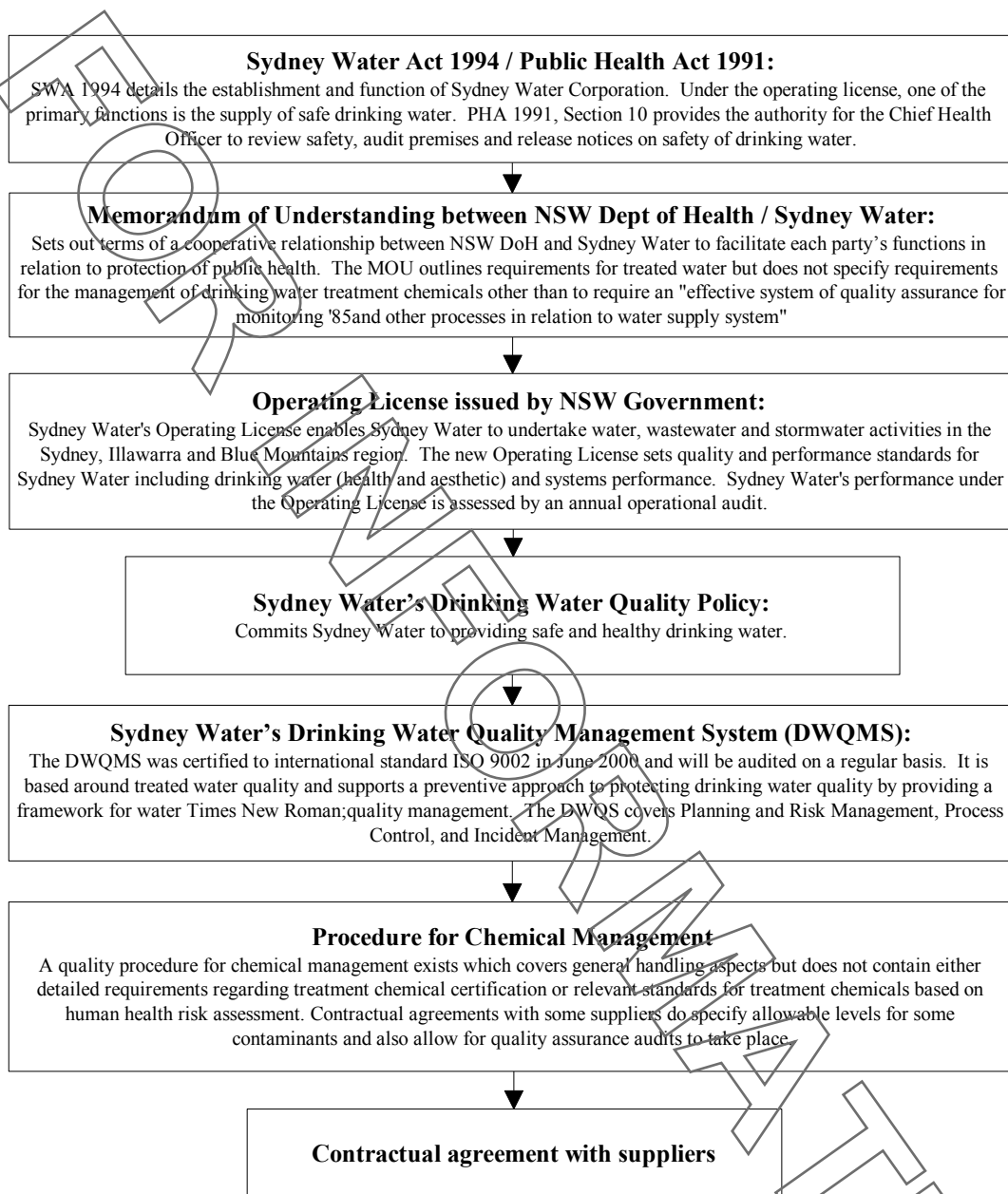
At the Federal level there is no specific instrument to regulate drinking water treatment chemicals (DWTC). In 1988, the NHMRC had a set of guidelines for drinking water treatment chemicals. The guidelines required companies to submit applications to the Secretary of the NHMRC Water Quality Committee. Applications were assessed based on efficacy and toxicology data supplied or generally known to be available. A list of approved substances was published in 1989 which indicated only seven¹⁰ chemicals were considered by

⁹ "Chemicals Used for Treatment of Drinking Water Supplies" (1989)

¹⁰ The NHMRC considered; calcium/sodium poly-phosphate silicate; ferric sulfate; polyaluminium chloride; polydimethylallyl ammonium chloride; polyacrylamides and acrylic acid; silver hydrogen peroxide; and, zinc ortho-phosphate between the period 1979 and

the NHMRC Water Quality Committee in the period 1979-1989. Since then, acceptance of drinking water treatment chemicals has been an ad hoc function of individual water suppliers.

Figure 3.1 Sydney Water Regulatory Overview



1989. Only one chemical was considered after 1988. The slow rate of evaluation and approval indicates these guidelines were not extensively used.

3.3 Processes Used by Water Suppliers for DWTC

The water suppliers are required by State legislation to provide safe drinking water and there is a growing emphasis on the control of chemicals. A survey of practices by water suppliers in Australia was not conducted as part of the scope of this work, however personal communication revealed some of the processes being used for chemical acceptance by water suppliers in Australia:

- Use of contractual arrangements with chemical suppliers and requirement for suppliers to conform to relevant standards.
 - According to the Australian Water Association¹¹, water suppliers generally require that chemicals entering water treatment plants meet NSF Standard 60 and 61¹² (protection of health) and/or AWWA
 - The water supplier Gippsland Water has generated a standard chemical supply contract that includes a technical specification for the standard chemicals being used. The contract also specifies that for some chemicals NSF certification is mandatory while for others it is recommended (“sought”)¹³. The detailed contract requirements regarding certification are apparently unique in Australia. It includes specifications for some but not all chemicals. In the absence of a specification in the Gippsland Water contract, the minimum standard required¹⁴ by this utility is the AWWA Drinking Water Standards or the technical specifications contained in the Drinking Water Chemical Codex.
 - Other water suppliers such as SA Water do have chemical specifications and testing requirements which suppliers must meet.
- Chemical control procedures within the water supplier’s quality system. As can be seen from figure 3.1 many water works have a process within their overall Quality Management System for handling chemicals. These systems concentrate on the storage and handling of treatment chemicals such that cross contamination does not occur and the correct dosage of the correct chemical at a particular point in time is used. The content and extent to which these ‘quality’ procedures require certification of chemical products to particular specifications is unknown.

3.4 Case Study of a Recent Evaluation of a DWTC

A review of new chemical assessments under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia revealed that one new chemical (see case study below) was assessed where the stated purpose was for treating drinking water. Acrylamide is currently undergoing an existing chemical assessment under NICNAS however it is unknown to what extent drinking water applications are to be evaluated.

¹¹ Personal Communication with Chris Davis AWA 21 September 2001

¹² Products claiming to be certified to NSF Standard 60 are meant to be either marked with, or their packaging contain the NSF Marking. Furthermore the NSF and other third party certifiers have widely available listings of certified products.

¹³ QSA A consulting arm of Standards Australia provide auditing in Australia on behalf of NSF International to assist Australian firms certify drinking water treatment chemicals.

¹⁴ Personal Communication Michelle Colwell Gippsland Water 13 November 2001.

CASE STUDY – MIEX®

- CSIRO Molecular Science, Orica Australia Pty Ltd and South Australian Water developed a resin technology called MIEX® that solves some water quality problems by effectively and economically removing natural organic matter prior to the water being disinfected. The resin was trialed in a 300 kl per day pilot plant in Adelaide, South Australia and in a 1 ML per day demonstration plant in Perth, Western Australia. The former was run by Orica and SA Water, and the latter by Orica and the West Australian Water Authority. Orica has completed construction of a commercial manufacturing plant at Deer Park in Melbourne, Victoria for the resin, and have signed contracts with the West Australian Water Authority to construct and supply resin for a 200 ML per day water treatment plant at Wanneroo.
- The water authorities in SA and WA interested in the new resin water treatment process proceeded with trials and further development on the understanding that the safety of MIEX would be assessed by an independent third party.
- Because in 1997 there was no other forum for it to be assessed prior to commercial introduction, MIEX resin was assessed under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)¹⁵. NICNAS requires chemical introducers to provide data on toxicology but does not assess efficacy. Normally for polymeric substances such as the MIEX Resin the NICNAS scheme does not require toxicology data to be submitted. However given that the resin was destined for use in public water supplies, extensive data on its use, inherent impurities (contaminants) and genetic toxicity data were voluntarily provided. The logic adopted for data acquisition was similar to the NSF Standard 61 and Australian Standard 4020 on Products for use in contact with drinking water. Health risk was judged by comparing calculated end-of-tap contaminant concentrations with maximum allowable contaminant levels specified in Australian or overseas drinking water guidelines. Where guidelines did not exist for a given impurity the manufacturer developed them in house. To maximise impurity leaching, solvent extracts of the product, rather than aqueous extracts, were tested in an *in vitro* bacterial point mutation assay and an *in vitro* eukaryotic cell micronucleus assay.
- A NICNAS certificate was obtained with the assessment report recommending that MIEX® comply with AS 4020.
- Primarily for overseas marketing purposes, NSF Certification was recently achieved using the same experimental toxicity data set as was supplied to NICNAS. MIEX® has been certified by NSF according to ANSI/NSF Standard 61 Drinking Water System Components – Health Effects.

Points to note:

- In the absence of a defined approach for evaluating drinking water chemicals in Australia, a framework developed for industrial chemicals was adapted for the purpose.
- Ultimately the NICNAS assessment certificate and assessment reports were regarded by the relevant State and Territory authorities as a third party independent review of public safety.
- Because MIEX involved a new and novel resin the approach adopted matched some of the philosophical aspects of intent of the NICNAS scheme. However since NICNAS evaluations are based on new chemical components of products, and not of the product itself, the scheme is probably not suitable for approval/evaluation of products or product brands (new or existing) as is done in overseas schemes for evaluation/certification of 'chemicals' used in the production of drinking water.
- Use of NICNAS inherently meant that effects on the environment were evaluated as part of the assessment of Miex and it was in this area that most controversy and delays occurred in issuing a certificate and report. It is noted that overseas drinking water chemical approval schemes do not include an environmental impact assessment as part of certification.

¹⁵ Chemical assessment programs under the Industrial Chemicals Notification and Assessment Act of 1989 provide for the assessment of both new and existing industrial chemicals prior to their introduction (importation and/or manufacture). The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is currently administered by the Department of Health and Ageing but in 1997 it was under the auspices of the National Occupational Health and Safety Commission (NOHSC).

The assessment process for new chemicals, now and then, is primarily directed towards assessing occupational health impacts but includes review of potential public health implications which is conducted by the Department of Health and Ageing. Assessment reports make recommendations including any restrictions or precautions relating to the lifecycle of the chemical. NICNAS does not assess efficacy or conduct a cost benefit analysis and the organisation does not have specific internal procedures for dealing with new or existing drinking water treatment chemicals.

- Presumably because of the absence of a considered philosophy and methods for the evaluation of drinking water chemicals, the evaluating body offered little practical assistance regarding what would be appropriate data for the evaluation. The manufacturer therefore took the primary lead in developing protocols for data acquisition for Miex. This led to increased costs in data acquisition and delays in evaluation.
- It is noted that most companies in Australia are not likely to undertake such development tasks.

3.5 Materials in Contact with Drinking Water.

Australian and New Zealand Standard AS/NZS 4020:1999, 'Products for Use in Contact with Drinking Water', Standards Australia, Standards New Zealand was first published by Standards Australia in 1992 as an interim standard (AS3855). It was re-designated AS 4020 and remained in an interim form following the second edition in 1994. In 1999 it was revised and designated AS/NZS 4020. The standard was prepared by joint Technical Committee CH/34, Materials in Contact with Drinking Water, and approved by Standards Australia and New Zealand Standards. The protocols in AS 4020 are based on the British standard, BS 6920. AS4020 is currently being revised and a draft will shortly be available for public comment. Although the current review focuses on processes for evaluating drinking water treatment chemicals, some of the features of AS 4020 are relevant for DWTC.

The standard requires material products in contact with potable water to meet minimum requirements for appearance, taste, and algal growth of aquatic microorganisms. In addition toxicology data is required on room temperature aqueous extracts of product material ie. "Cytotoxicity Activity of Water Extract" (no reference cited in the standard for the cytotoxicity methodology but it is assumed the requirement is based on the cultured mammalian cell test in BS 6920) and "Mutagenic Activity of Water Extract (OECD Guidelines 471 & 472)".

4. Canadian Initiatives for Evaluating Chemicals in Contact with Drinking Water

In Canada the provinces and territories are responsible for the safety of drinking water supplies in their jurisdiction whereas at a federal level Health Canada plays a key leadership role, conducts research and surveys drinking water quality. Neither the provinces/territories nor Health Canada have produced unique processes for the evaluation of drinking water treatment chemicals. However federal-provincial collaboration is well advanced in the development and promulgation of guidelines for ensuring quality and public safety of DWTC.

Specific activities in Canada in relation to evaluation processes for drinking water treatment chemicals include:

- In response to requests from the provinces and territories, during 2000 Health Canada introduced to parliament a Bill entitled the *Drinking Water Materials Safety Act* 1997 (Giddings 2000). This bill was not passed¹⁶ and its reintroduction is being considered by Health Canada. The *Drinking Water Materials Safety Act* would have established certification requirements for all products that come in contact with drinking water, from its collection to the consumer, and included drinking water treatment devices, drinking water treatment additives and distribution system components. The intent of the Bill and attending regulations was to incorporate the relevant ANSI/NSF Standards by reference and regulate drinking water materials from the point of retail (Giddings 2000);
- The WHO (2001) states that some provinces/territories have adopted ANSI/NSF Standards 60 and 61, however during this review no Canadian legislative reference to ANSI/NSF, either federally or at the provincial/territorial level, was found;
- Health Canada recommends that “where possible”, water utilities and consumers use drinking water materials certified as conforming to the applicable ANSI/NSF health based performance standard (Health Canada 2000);
- ANSI/NSF Standard 60 and 61 have been adopted by the Canadian Standards Association and the Standards Council of Canada have accredited three organisations to certify drinking water materials against the ANSI/NSF Standards (Health Canada 2000):
 - CSA International;
 - NSF International; and
 - Underwriters Laboratories.
- In 2000, Health Canada conducted a survey on drinking water treatment devices intended to disinfect water contaminated by microorganisms, improve the taste, odour and appearance of water, and/or remove chemical contaminants. The study creates a profile of drinking water treatment devices available to Canadian consumers in the autumn of 1999. Of 318 device models identified, 62% were not certified, 34% were certified and 4% were not NSF certified but nonetheless bore the NSF name/logo. Although the survey was of water treatment devices for consumer use which are not within the scope of this review, the results are interesting regarding industry conformation with the recommendations of Health Canada, viz.
 - Although Health Canada recommends ANSI/NSF Certification, 62% of products were not certified.

¹⁶ Personal communication with Health Canada 24 September 2001 suggested that one of the reasons the bill may not have passed was industry concern regarding costs and resources involved in certification of products to ANSI/NSF Standard 60.

- 4% of products misrepresented their status as certified, when in fact they were not.

FOR INFORMATION

5. Status of Requirements for Evaluating Materials in Contact with Drinking Water in New Zealand

In New Zealand the regional councils are responsible for provision of safe community water supplies. At a federal level the Ministry of Health provides the key leadership role and surveys of drinking water quality. The primary code for protecting the safety of drinking water supplies in NZ, are the Drinking Water Standards for New Zealand. These Standards are 'end of pipe' and were developed by the Ministry of Health with the assistance of an expert working group. Extensive use was made of the World Health Organization's *Guidelines for Drinking-Water Quality* and addenda up to 1998. Reference was also made to the previous *Drinking-Water Standards for New Zealand* 1984 and 1995, and to the *Australian Drinking Water Guidelines* 1996 (Ministry of Health 2000).

Neither the regional councils nor the Ministry of Health have produced unique processes or requirements for the evaluation of drinking water treatment chemicals. Personal communication with the Ministry of Health indicated that the evaluation and control of drinking water treatment chemicals would be aligned with WHO and Australian evaluation procedures¹⁷.

The New Zealand Water and Wastewater Association (NZWWA) have produced quality standards for five drinking water treatment chemicals (hydrated lime, aluminium sulphate, fluoride, EPI-DMA polyelectrolytes and chlorine). The standards are similar to the CEN Standards of Europe and the AWWA Standards of the USA. Their main purpose is to provide purchasers, manufacturers and suppliers with guidance on minimum technical attributes of the chemicals plus physical and chemical testing requirements.

¹⁷ Personal communication with Ministry of Health Officer 21 November 2001

6. UK Provisions for Evaluating Material in Contact with Drinking Water

6.1 Overview

A schematic overview of the United Kingdom process for evaluating chemicals in contact with drinking water is provided in Figure 6.1. The Committee on Products and Processes for Use in Public Water Supply (CPP) assesses products on the basis of health and aesthetic impacts but not technical merits, and advises the Drinking Water Inspectorate (DWI) of chemicals and materials recommended for approval. The DWI, in turn issues approval letters and publishes a yearly list of approved DWTC. Water Supply/Quality regulations specifically prohibit use of non-approved products, and DWI audits water supply companies for compliance with the regulations. CPP/DWI produce application forms and guidance documents to assist applicants in providing submissions to CPP. Water supply companies may use chemicals not on the UK approved list only if they comply with a European standard (BS:EN) and the product supplier provides documentation of compliance to BS:EN, or they meet certain exemption requirements. Details of the operation and remit of CPP are described below.

The UK DWTC approval system is unique in that product compliance audits are carried out by the approval agency (DWI) on the water supplier rather than the product supplier. Furthermore the requirements are specified in legislation rather than in national Standards.

6.2 Regulatory Background

Regulations 25 to 28 of the Water Supply (Water Quality) Regulations (1989) deal with the application and introduction of substances and products used in the treatment and distribution of water supplies.

Under these regulations (specifically Regulation 25) a water supplier shall not, other than for the purposes of testing or research, use a product in contact with drinking water unless it:

- has been approved by the Authorities [Regulation 25(1)(a)], or
- is considered by the water company to be eligible for exemption under Regulation 25 (1) (b) and considered by the water company to be unlikely to adversely affect the quality of water¹⁸ eg. small surface area, or under Regulation 25 (1) (c), i.e. the traditional use exemption where the chemical or material has been used during the twelve months prior to July 1989.
- was approved under the former voluntary scheme and is used in accordance with any relevant conditions of approval.

The Authorities are the 'Secretary of State for the Environment, Transport and the Regions' and 'The National Assembly for Wales'. These Authorities delegate administration of, and compliance with the regulations to the 'Drinking Water Inspectorate' (DWI). The Secretary of State has powers to revoke or modify approvals previously made, and unless it is in the immediate interests of public health, six months notice is usually given of any modifications to approvals.

¹⁸ Presumably the water company needs to conduct and record a health risk assessment to attest to the low likelihood of adverse impact on the water.

The Water Supply Regulations make provision for:

- annual publication of a complete list of approved products;
- a technical audit and inspection of water companies which includes an assessment as to whether substances and products are being used in accordance with requirements of regulation 25 and approval conditions; and
- prosecution of a water company for contravention of the regulations. DWI has produced an overall guidance document to assist water companies to comply with the regulations. This guidance document is also used by DWI as the basis for conducting compliance audits of water companies.

The DWI performs these tasks on behalf of the Authorities and is therefore the technical regulator for the privatised water companies in the UK. The DWI also represents the Authorities at European Union discussions on the development of harmonised standards for drinking water contact materials.¹⁹ The European Standards Institution (CEN), under European Union Legislation, is developing these harmonised standards. The standards have a designation of BS:EN, and water treatment chemicals that conform to a BS:EN may be used by water companies without the approval of the Authorities, provided that any national conditions of use are observed.²⁰

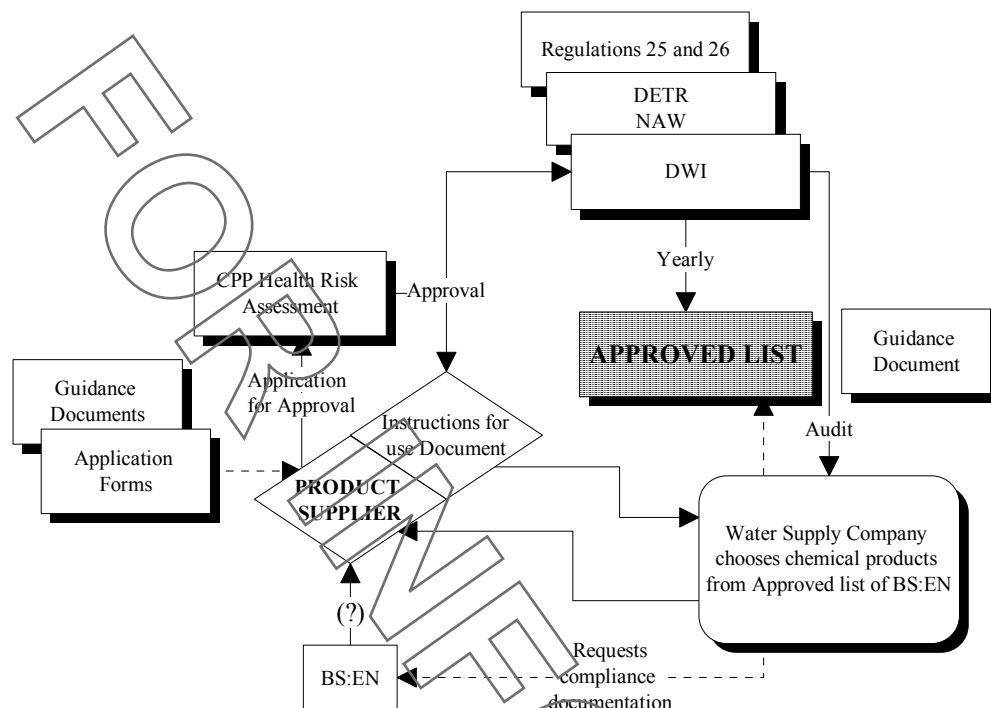
¹⁹ In 1999 the European Commission established the Regulatory Group - Construction Products Drinking Water (RG-CPDW) to be responsible for the development of an European Acceptance Scheme for construction products in contact with drinking water. It is the current understanding of Toxikos that this scheme does not include chemicals used in the production of drinking water.

CEN have conducted a workshop to develop an international consensus on the overall approach to the health-based toxicological assessment and approval of membrane water treatment systems for the preparation of public drinking water supplies. The focus of the assessment and approval was on the potential adverse effects on water quality and public health caused by migration of substances originating from the membrane systems. Consensus has been achieved and published as CWA 14247:2001 in July 2001. CEN Workshop Agreements (CWAs) are not standards but may be the first attempt to prepare a standard. Toxikos has been unable to obtain a copy of CWA 14247:2001.

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- This is interpreted as meaning the water company must comply with dose rates, or other directions of use as set by CPP when the product is used in the UK, even though different dose rates/conditions of use may have been approved elsewhere in the EU. The same would apply in other EU countries, for example the use of polyelectrolytes has been banned in Switzerland, even though they conform to a BS:EN standard, but they may be used in France at specified dose rates.
- There seems to be a dichotomy in this condition; if chemicals comply with a BS:EN they do not have to be approved by CPP, yet if CPP do not access and assess the data on these chemicals, how are national conditions of use established? Nevertheless if conditions of national approval affect the marketing of products that are subject of a European Standard the UK is obliged to notify the EC (how?) as required by Directive 98/34/EC on the notification of new technical requirements.
- EU Directive 80/778/EEC on drinking water sets quality standards for drinking water, it has provided governments and water suppliers with a stable and predictable base for their investment programmes. At this time Toxikos presumes EU processes for approving chemicals for use in drinking water are under the umbrella of 80/778/EEC.

Figure 6.1: Overview of UK approval process for evaluating materials (inclusive of chemicals) in contact with drinking water



Notes:

Under regulations 25 & 26 of Water Supply (Water Quality) Regulations 1989, suppliers of public water may use either products from the approved list or those which are subject to British/European standard (a BS:EN). On application, and provision of specific information, a product supplier may have a product approved by CPP on the basis of no adverse effects (health and aesthetics) to the delivered water. An approved product list is published yearly.

- DETR = Secretary of State for the Environment, Transport and the Regions
- NAW = The National Assembly for Wales
- DWI = The Drinking Water Inspectorate
- CPP = The Committee on Products and Processes for Use in Public Water Supply

6.3 The Committee on Products and Processes for Use in Public Water Supply

The CPP is an advisory committee with the status of a ‘Jointly Established Body’ administered by England, Wales and Scotland. CPP evaluates applications for approval of products to be used in drinking water production and advises the Authorities, via DWI who in turn issue the approval notices.

Membership:

Chairperson plus four members with expertise in engineering, materials science, toxicology, and water treatment, and another one who is a ‘consumer interest’ advocate. In addition there are two advisers, one on public health (from the Department of Health) and one on policy/administrative aspects of the regulations (from DWI). DWI supplies a technical secretary and assistant.

Purpose:

To ensure that chemicals and construction materials²¹ do not cause adverse effects on drinking water quality;

On application by an individual/entity, CPP evaluates chemicals and materials for use in drinking water, and²²

CPP does not evaluate the technical merits (ie. efficacy) of a product, and specifically points out that approval of a product is given on grounds of no objection on health criteria or no other adverse impact on water quality. Approval by CPP is not an endorsement of efficacy:

- CPP meets every two months;
- In 2000, 40 products were approved, 2 were rejected;
- The CPP technical secretariat addressed approximately 1,060 inquiries in 2000;
- Note, not all the above workload relates to approval of chemicals; and
- CPP has the ability to recommend that DWI commission studies to be conducted²³. For example in 2000, CPP commissioned a mutagenicity testing study, and a study of compliance of products on the UK approved list with the EU standard 1999 BS:EN for activated carbon filtration media

Interaction with European Standards:

Water treatment chemicals that conform to a BS:EN standard can be used by water companies without Authority approval²⁴.

Designated laboratories:

CPP approves materials, as well as chemicals, which may come in contact with water while it is being delivered to the public. BS 6920: 2000 is the standard applicable to these materials. CPP only accepts results from tests that have been performed by laboratories accredited for conducting BS 6920 tests [see footnote 23].

6.4 UK List of Approved Products

The list [approved under regulation 25 (I) (a)] is published on the DWI web site (<http://www.dwi.gov.uk/soslist/pagea.htm>) in December each year

²¹ For construction materials and protective coatings used in connection with public water supplies, CPP requires the results of BSN 6920 tests (or equivalent European tests). BSN 6920 includes separate tests for effects on water taste, appearance, organism growth, leaching of metals and cytotoxicity. This standard forms the basis of the Australian Standard AS4020:1999, 'Products for Use in Contact with Drinking Water'.

²² CPP is concerned with products/materials used in provision of public water supplies, materials used within consumer premises must comply with 'The Water Regulations Advisory Scheme' operated by the WRc Evaluation and Testing Centre. The scheme tests fittings and materials to establish whether they satisfy the Water Supply (Water Fittings) Regulations 1999. Methods and criteria specified in BS 6920:2000 are applicable but only laboratories accredited by the UK Accreditation Service (UKAS) for BS 6920 testing may carry out these tests.

²³ To date no recommendation by the CPP to DWI for research studies have been rejected. Personal communication with the secretariat of CPP.

²⁴ BS:EN for drinking water chemicals do not contain any mandatory requirements for attestation of conformity. Water companies are expected by the Authorities to stipulate appropriate attestation requirements in their procurement contracts.

Until recently the list contained all chemicals and materials evaluated by CPP from September 1989 onwards, now it only lists substances and products that are not the subject of a European Standard²⁵ (BS:EN).

Table 3.1 provides an indication of the structure and contents of the UK list of approved products.

Two general conditions of approval are attached to all approved substances and products that appear on the UK list:

- That use is in accordance with the ‘Instructions for Use’ document. Approval holders must provide water companies with copies of the ‘Instructions for Use Document’ that was considered by the Committee when approval was recommended;
- That the approval of the Authorities is obtained in respect of the following:
 - any change in the formulation of the approved product;
 - any change in source or identity of raw materials;
 - any change in the manufacturing process, including location of manufacture
 - any change in designation of the approved product; and
 - any change in name or ownership of the organisation holding the approval.

British/European standard BS:EN 1420-1:1999, the “Determination of odour and flavour assessment of water in piping systems” deals with the influence of organic materials on water intended for human consumption. It is presumed that with regard to aesthetic impact, chemicals used in water treatment are also covered in this standard but this has not been verified.

CPP has two application forms for its deliberations, one is for “Approval of a chemical”, the other for “Approval of chemical additives for use in contact with membrane filtration and distillation systems”. Although the information requirements for the different types of chemical are slightly different, Table 6.2 provides an indication of the sort of information requested for approval of a chemical. DWI also provides guidance documents²⁶ to assist applicants or their consultants.

The guidance documents contain an overview of the approval systems and plain English descriptions and interpretations of the regulatory environment governing the approval process(es), decision tree guidance on the route to approval, information requirements for chemicals and products, examples of typical classes of low contact area products eligible for exemption, and copies of all the letters issued for revision of conditions of use of chemicals and products. Despite the guidance documents being available, CPP recommends applicants obtain assistance from experienced consultants if they are uncertain about requirements or interpretation of test results.

²⁵ Presumably as more EU standards for chemicals in contact with drinking water are created, there will be progressively fewer entries on the UK list, suggesting that in the long term the UK listing for chemicals will dramatically change from its current appearance. Toxikos has been unable to locate a central EU listing.

²⁶ The guidance documents are “Guidance on Regulatory Requirements Concerning Substances and Products used in the Treatment and Provision of Public Water Supplies”, Guidance Regulation 25-rev1998; and “Guidance to Applicants Seeking Approval of Products and Processes for use in the Treatment and Provision of Public Water Supplies”, Issue 3 - August 2001.

CPP assesses the product information with respect to adverse effects and potential risks to consumers' health, and also whether the proposed product use is consistent with current regulations and water industry practices. This appears to be done by expert deliberation since specific guidance for the risk assessment process does not appear to exist.

It is apparent that the CPP conducts a health risk assessment for chemical products submitted for assessment but the form of the risk assessment and equations used are not available. It is suspected that equations similar to those used by NSF (see Chapter 7) which have been sanctioned by WHO (see chapter 2) are employed.

Table 6.1: Contents and brief notes on the UK “List of Substances, Products and Processes Approved under Regulations 25 & 26 for Use in Connection with the Supply of Water for Drinking, Washing, Cooking and Food Production Purposes”

Part I	Chemicals that <u>are</u> the subject of a European Standard (BS:EN) <u>and</u> national conditions of use. [Entries specify the BS:EN standard to which the product must conform].	Generic subject listings in Parts I and II. <ul style="list-style-type: none"> • Flocculants and coagulants • Adsorbents • Ion exchange resins • Other chemicals • Products for disinfection and cleaning of water works apparatus including distribution systems • Products for emergency use • Traditional chemicals
Part II	Chemicals not the subject of a current European standard (BS:EN). [In Parts I, II and III there are generic listings (see box) containing sub-listings (eg. Flocculants – products based on aluminium) with entries of company name and products they offer]	
Part III	Construction products [In Parts I, II and III entries specify dosages and/or summarise other conditions of use].	
Part IV	Membranes and Filters	
Appendices	<ul style="list-style-type: none"> • Changes to approvals – including a list of current British/European (BS:EN) standards. • Regulations 25 & 26. • Amendments to list of approved substances and products. • Contractors approved for the <i>in situ</i> application of polymeric coatings. • Listings: <ul style="list-style-type: none"> - Manufacturers’ and suppliers addresses - Manufacturers and suppliers index - Product index [Within the ‘List’ there is cross indexing between sections]	

Table 6.2: Brief overview of information requested on the CPP application form for approval of a chemical.

<p>Section 1 – General</p> <ul style="list-style-type: none"> • Product name • Applicant's name and address • Contact details of consultant authorised to assist with application approval. • Type of product • Description and function of product • Statement of effectiveness • Description of method of use • Normal and maximum dosage rates • Points of application • Dosage method and control • Method for determining concentration of product and impurities in water. • Reactions with other water treatment chemicals • Manufacturer's official instructions for use • Type(s) of use for which approval is sought 	
<p>Section 2 – Product Formulation</p> <ul style="list-style-type: none"> • Formulation • Names and addresses of suppliers of formulation components • Description of manufacturing process • For polyamines, residual amounts of certain monomers • Product technical specifications 	
<p>Section 3 – Toxicological Data</p> <p>[All or some of the following may be required depending on the type of chemical and CPP's requirements for risk assessment].</p> <p>Toxicokinetic studies and metabolism data of product components:</p> <ul style="list-style-type: none"> • Acute studies, LD₅₀ etc • Developmental toxicity • Carcinogenicity studies • Sub-acute (90 day) • Mutagenicity (<i>in vitro</i> & <i>in vivo</i>). • Dermal toxicity (irritancy & sensitisation). 	
<p>Section 4 – Information on disposal and fate</p>	
<p>Section 5 – Approvals from other approval organisations</p>	
<p>Section 6 – Declarations</p>	

7. Summary of USA Provisions for Evaluating Material in Contact with Drinking Water

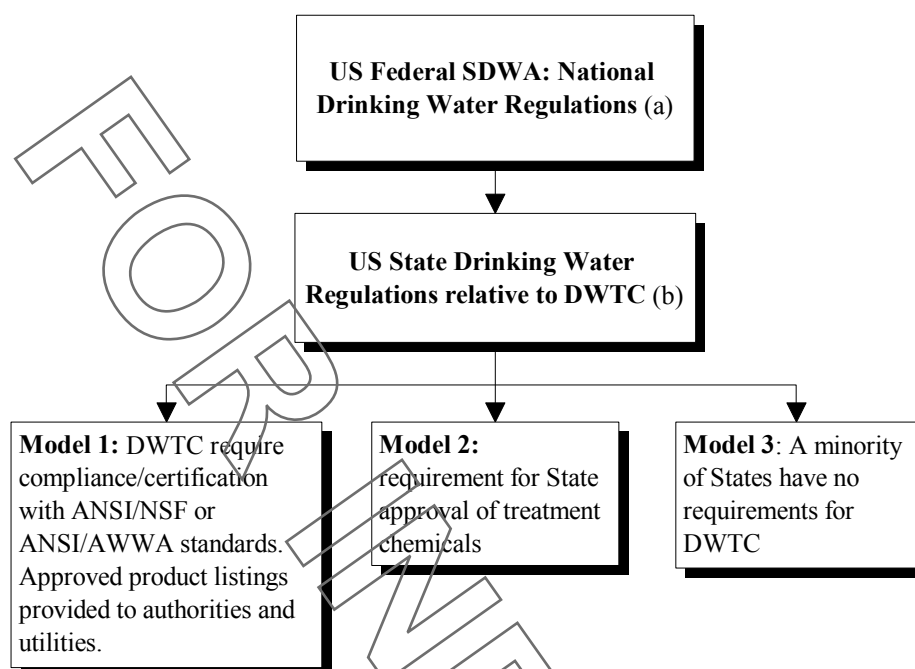
7.1 Overview

A schematic overview of the processes in the USA for evaluating chemicals in contact with drinking water is provided in Figures 7.1 and 7.2. The Federal Safe Drinking Water Act (SDWA) requires US States to take primary responsibility for ensuring drinking water quality is achieved. Unlike the UK and The Netherlands, no specific regulatory framework for drinking water treatment chemicals exists at a federal level. Many States do include specific provisions for drinking water treatment chemicals (DWTC) within their Safe Drinking Water regulations (SDWR) and rules. While the approach varies from State to State, it is possible to generalise about the approaches. Most States require compliance to relevant standards, which in the case of DWTC are published by the National Sanitation Foundation (NSF International) and the American Water Works Association. At least one State requires approval of new drinking water treatment chemicals by the relevant state authority, and a minority of States do not include specific requirements for DWTC.

There are two types of standards used to specify requirements for DWTC. The AWWA has developed standards for all traditional treatment chemicals. These standards detail minimum chemical requirements. NSF International develops and publishes ANSI/NSF Standards 60 and 61 at the request of the US Environmental Protection Agency. The ANSI/NSF standards detail minimum requirements for the control of potential adverse human health effects.

According to a survey conducted by the Association of State Drinking Water Administrators (ASDWA), 41 states now require either by legislation, regulation or policy, that products be certified to ANSI/NSF Standard 60/61 by an ANSI accredited certification agency (NSF 2000). NSF International (2000) has estimated that 80% of drinking water treatment chemicals in the USA are certified. Details of regulatory frameworks and standards are provided below.

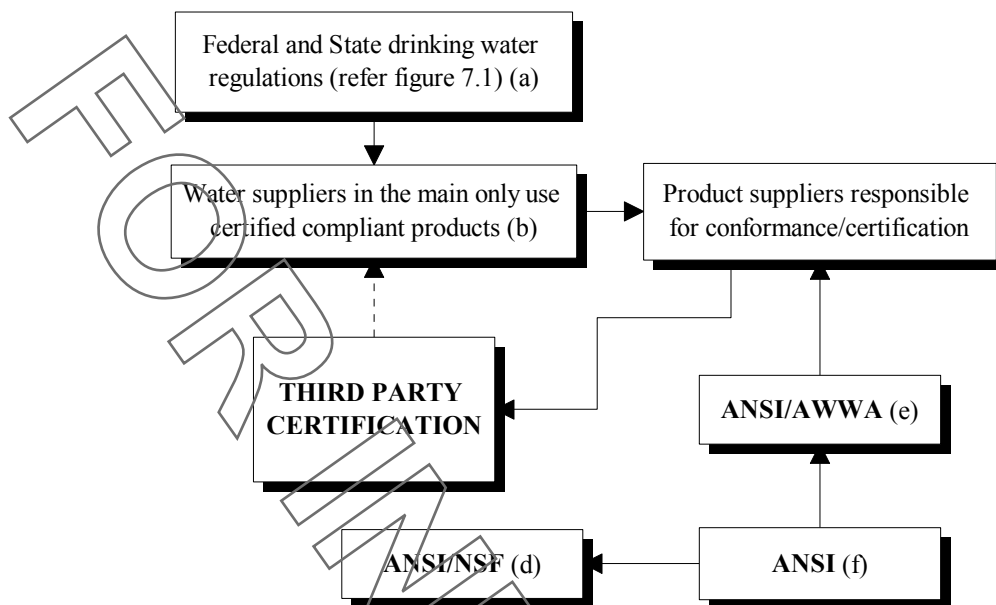
Figure 7.1: Overview of USA Regulatory Framework for drinking water chemicals (DWTC).



Notes Figure 7.1

- a The Safe Drinking Water Act (SDWA) is the principal law in the US governing drinking water safety. It authorises the (US EPA to establish national drinking water regulations.
- b States are primarily responsible for enforcement of the SDWA and national drinking water regulations. The States must implement regulations which are equivalent or more onerous than the NDWR established by the USEPA. The States set specific requirements for water suppliers. For DWTC State regulations take one of three approaches: specify requirement for ANSI/NSF 60/61 approval (or equivalent); require approval by a specified competent authority; or, do not specify any requirements. There are three broad models pertaining to DWTC (see also figure 7.2):
- Model 1.** An ANSI accredited third party certifier (eg. NSF International) certifies products. This involves review and analysis of the product, and audits of the manufacturing facilities. Changes to the manufacture of the certified product must be approved by the certifier. NSF certification is predominantly based on a health-based assessment of anticipated impurity levels in treated drinking water. A product listing is updated twice yearly. AWWA standards are quality standards for generic treatment chemicals that are also used to standardise quality of treatment chemicals. There is no certification or approval of product brands thus the onus is on the chemical brand supplier to attest compliance with the relevant AWWA Standard.
- Model 2.** Various States do not include a specific reference to any standards but do specify that an approval is required from a competent authority. For example the US State of Connecticut requires the Commissioner of Health to approve DWTC.
- Model 3.** A minority of US States do not have specific rules/regulations for drinking water treatment chemicals.

Figure 7.2: Overview of Compliance /Certification Framework for chemicals against ANSI/NSF or ANSI/AWWA Standards



Notes Figure 7.2

- a. The Association of State Drinking Water Administrators (ASDWA) conducts an annual survey on State adoption of ANSI/NSF Standards 60 and 61. The latest survey (2000) found that 43 States have legislation, regulation, or policies mandating that products meet the requirements of the ANSI/NSF standards. Forty-one of these States require that products be certified to Standards 60 or 61 by an ANSI-accredited certification agency. NSF International estimates that 80% of products sold in the USA are certified.
- b. State regulations require water suppliers to ensure products used in drinking water treatment are certified. The water suppliers in turn require product suppliers to verify that products meet ANSI/NSF Standards, are certified and also require conformance to the ANSI/AWWA standards.
- c. Water suppliers can confirm that a product is certified as the product packaging for a certified product includes a mark of the certifying body, in addition the certifying bodies maintain lists of certified products that include supplier details. These lists are made available to water suppliers. Confirmation of conformance with ANSI/AWWA standards is more difficult as no certification is required. Product suppliers often produce certificates of analysis attesting to compliance however it is uncommon that each delivery or batch is tested (Casale 2000).
- d. ANSI/NSF Standards 60/61 are health based and have been developed to establish minimum requirements to control potential adverse health effects from products added to potable water. It does not include the product performance requirements that are specified by American Water Works Association (AWWA) Standards or American Society for Testing Materials Standards, nor does it evaluate taste and odour. Table 7.1 outlines the contents of the standard. Figure 7.3 outlines the critical decision making steps in the evaluation process stipulated by the Standard. The standard is based on two critical components: product analysis to determine a normalised “at-the-tap” concentration and toxicology review to determine a health based guideline values, called Single Product Allowable Concentration (SPAC), for product components.
- e. AWWA standards provide minimum requirements for drinking water treatment chemicals. By compound, these standards describe a chemical’s origin, physical properties, and how it is used in water treatment. Additionally, each standard recommends various tests to verify treatment chemical quality and concentration requirements. Compliance with these standards is voluntary; that is, they are not made mandatory by AWWA. But, the standards can and have been made mandatory by utilities and regulatory agencies. AWWA standards are not specifications. By itself, a standard doesn't provide all the information necessary for a manufacturer, supplier, or constructor to know exactly what the purchaser requires. A standard may not have

provisions for all parts of a project. AWWA standards do not provide for certifications or approvals of any product. Unlike NSF, AWWA doesn't test any product in developing or approving a standard (AWWA 2001).

f. ANSI is the American National Standards Institute. In the US the two major organisations that publish standards for drinking water treatment chemicals are NSF and AWWA. All drinking water treatment chemical standards produced by these organisations are ANSI-accredited.

7.2 Regulatory Background

The Safe Drinking Water Act (SDWA) provides a framework for the regulation of drinking water supply in the USA (US EPA 1999). The SDWA includes requirements concerning source water protection, treatment, distribution system integrity and public information but does not specifically regulate drinking water treatment chemicals (DWTC). Prior to 1985, the US EPA did approve DWTC, however the US EPA decided to fund the establishment of a third party certification program for DWTC, that now exists as the ANSI/NSF Standard 60/61 (NSF International 1999).

The SDWA is regulated by the USEPA through the National Primary Drinking Water Regulations (NPDWR) that set national standards for drinking water quality. These regulations establish enforceable Maximum Contaminant Levels (MCL) for specific contaminants in drinking water and define methods for water treatment and removal of contaminants. The regulations also set Secondary Maximum Contaminant Levels (SMCL) or aesthetic quality parameters for taste, odour, colour and appearance. SMCLs are established by the US EPA as advisory guidelines and are not enforceable standards.

The regulations place the onus on the water supplier to test and monitor their water systems for contaminants in order to ensure that the standards are achieved. The enforcement of these regulations is conducted by state drinking water authorities that are normally part of the State Health Department or Environmental Protection Authority. The State applies to the US EPA for the authority to implement the SDWA within their jurisdiction. They are approved by the US EPA if they can show that they will adopt standards at least as stringent as the national guidelines and can ensure that water systems meet these standards. All states except Wyoming and the District of Columbia have received authorisation to implement SDWA.

In enforcing the SDWR the States are responsible for ensuring that water suppliers test for contaminants, provide plans for water system improvements, conduct on-site inspections and sanitary surveys, provide training and technical assistance and take action when the water systems do not meet standards (AWWA 1999, USEPA 1999).

With regard to drinking water treatment chemicals and products in contact with water the States have adopted several approaches. These approaches are exemplified below by Models A and B.

Model A: US State of Arizona

Arizona Rule (R18-4-119) (Arizona 1995) specifies that all products added directly to water during production or treatment shall conform with NSF/ANSI Standard 60/61. The Rule requires evidence (i.e. an NSF Listing/Certification Mark) of conformance with ANSI/NSF 60/61 to be present on the product or product packaging. Marks of conformance are the primary gauge for whether a product has been certified²⁷.

An exception is allowed under the Rule: The responsible agency can consider alternative standards for chemicals, materials, or equipment as complying with the standards required by this Section of the Rule if the chemicals, materials or equipment are essential to the design, construction, or operation of a drinking water system and are not available from more than one source.

The alternative standards are listed as:

- Protection Agency, the Food and Drug Administration, or other federal agencies as appropriate for addition to potable water or aqueous food;
- Products composed entirely of ingredients listed in the National Academy of Sciences "Water Chemicals Codex"²⁸;
- Products are consistent with the specifications of the American Water Works Association;
- Products designed for use in drinking water systems that are consistent with the specifications of the American Society for Testing and Materials; and
- Products historically used or in use in drinking water systems, and consistent with standard practice, which have not been demonstrated during past applications in the United States to contribute to water contamination.

Model B: US State of Connecticut

Section 19-13-B80 of the State of Connecticut Public Health Code (Connecticut 1995) requires that no chemical substances be added to public water supplies unless approved by the Commissioner of Health.

Chemicals shall be applied to the water at such points and by such means as to:

- assure maximum efficiency of treatment;
- assure maximum safety to consumer;
- provide maximum safety to operators;
- assure satisfactory mixing of the chemicals with the water;
- provide maximum flexibility of operation through various points of application, when appropriate; and
- prevent backflow or back-siphonage between multiple points of feed through common manifolds.

The regulations do not require certification to any particular standard, however guidance document, "Drinking Water Additives and System Components" (Connecticut WSS 1997) specifies that it is the policy of the State of Connecticut Water Supplies Section that:

"Any chemical substances and system components should meet ANSI/NSF standards 60 and 61, respectively. Presently, NSF and Underwriters Laboratory (UL) have published listings that meet these standards."

Thus the requirement for certification is not specifically legislated nor mandatory but is the policy of the key regulator in the State of Connecticut.

²⁷ In a survey by Health Canada (2000), 4% of water treatment devices with an NSF marking were not actually certified by the NSF. The incidence of bogus markings for DTWC is not known.

²⁸ In 1982, a Water Chemicals Codex was published listing the recommended maximum impurity content (RMIC) for each drinking water treatment chemical. The codex is commonly used in the industry. It has not been revised since 1982.

7.3 American National Standards Institute (ANSI)

ANSI is a private, non-profit organisation that administers and coordinates the US voluntary standardisation and conformity assessment system. ANSI is the official US representative to the International Accreditation Forum (IAF), and the International Organization for Standardization (ISO).

In the US the two major organisations that publish standards for drinking water treatment chemicals are National Sanitation Foundation (NSF) and American Water Works Association (AWWA). All drinking water treatment chemical standards produced by these organisations are ANSI-accredited.

ANSI-accredited standards are usually developed by a balanced committee of stakeholders and are subjected to a public review process administered by ANSI. This is similar to the Australian Standards process.

Alternatively ANSI can approve an organisation to produce an ANSI Standard. ANSI have approved NSF International as an “auditor designator”, meaning that NSF standards automatically become ANSI Standards. In contrast, AWWA standards undergo additional review steps before they are ANSI designated.

ANSI uses third parties to provide certification against their standards (see Section 4.5).

7.4 National Sanitation Foundation (NSF)

NSF International, founded in 1944 as the National Sanitation Foundation, is known for the development of standards, product testing and certification services in the areas of public health, safety and protection of the environment. It is an independent, non-profit organisation providing a range of services around the world. While focusing on food, water, indoor air and the environment, NSF develops national standards and provides third-party conformity assessment services while representing the interests of all stakeholders. The primary stakeholder groups include industry, the regulatory community and the public at large.

In 1985 the Drinking Water Additives Program (DWAP) was initiated with a cooperative agreement from the US EPA. Since then NSF has received accreditation by the American National Standards Institute (ANSI) for its product certification programs. The NSF has formal status for its standards in The Netherlands and the Canadian Standards Association. It has been a collaborating centre on drinking water safety and treatment with the WHO since 1996.

7.5 Overview of NSF (ANSI/NSF Standard 60 - Health Effects) Certification Process

Prior to 1988 the US EPA issued letters of approval to manufacturers for products (including chemicals) intended to be in contact with drinking water. The process involved review of formulations only and did not include product testing or inspections of manufacturing facilities. With the intention of replacing its ‘in-house’ approval process, the US EPA in 1984 contracted for the development of external standards and certification program for

products intended to be in contact with drinking water. The contract was awarded to a consortium of stakeholders, which included the AWWA (American Water Works Association), AWWARF (AWWA Research Fund), the ASDWA (Association of State Drinking Water Authorities, and NSF. In 1988 the ANSI/NSF Standard 60²⁹ was first published, followed soon after by ANSI/NSF Standard 61.

ANSI/NSF Standard 60 was developed to establish minimum requirements for the control of potential adverse health effects from products added to water for its treatment. It does not evaluate taste and odour, nor does it include product performance requirements; these are specified by American Water Works Association Standards and American Society for Testing Materials Standards. Table 7.1 outlines the content of the Standard.

Figure 7.3 outlines the basic decision making steps required by the Standard. The Standard is based on two critical components:

- product analysis to determine a normalised “at-the-tap” concentration; and
- toxicology review to determine a health based guideline value for constituents and impurities called Single Product Allowable Concentration (SPAC).

ANSI provides accreditation and approval for organisations to provide third party certification services. ANSI ensures the competency of these third party certification bodies through a process of conformity assessments. The third party service provider formally applies to ANSI, who in turn audits the provider to assess the adequacy of the organisation to provide certification against a particular ANSI Standard.

For ANSI/NSF Standard 60 and 61 the following organisations are listed by ANSI as accredited certification bodies:

- CSA International (Canadian Standards Association);
- International Association of Plumbing & Mechanical Officials (Standard 61 only);
- NSF International; and
- Underwriters Laboratories Inc.

NSF International is therefore one of four organisations authorised in the USA to operate a certification program based on Standards 60 and 61. NSF currently lists over 12,525 product brands as being certified to ANSI/NSF Standard 60 (NSF International 2000).

Figure 7.3 depicts the technical procedure used for evaluation of products³⁰. NSF toxicology staff review the product/material information submitted by a manufacturer to identify all potential contaminants that may be added to drinking water resulting from the material’s use. A factory audit is used to confirm manufacturing processes. During the audit, formulations and suppliers are verified, QA/QC records are audited, the product/material and raw materials are sampled by NSF staff for testing in the NSF labs. The sampled product/material is tested according to the protocols outlined in the ANSI/AWWA Standards.

²⁹ ANSI/NSF Standard 60 – Drinking Water Treatment Chemicals – Health Effects. 2001, American National Standards Institute (ANSI)/National Sanitation Foundation (NSF) International.. NSF International Ann Arbor, Michigan USA.

ANSI/NSF Standard 61 – Drinking Water System Components – Health Effects. 1999 . American National Standards Institute (ANSI)/National Sanitation Foundation (NSF) International. NSF International Ann Arbor, Michigan USA.

³⁰ Note that the evaluation and certification process is for proprietary product brands and not for generic chemicals. Technical attributes DWTC are stated in the NSF/AWWA standards for generic chemicals.

Following laboratory testing, contaminant concentrations are "normalised" or converted to at-the-tap concentrations and compared to the standard's maximum allowable level (MAL). If the results are acceptable, NSF and the manufacturer enter into a contractual agreement and the product is certified and listed by NSF. The NSF authorised formulations are retained at the product facilities. Manufacture of the authorised formulation may only be changed by advance written notice and approval by the NSF.

After the initial certification, production facilities are audited unannounced and certified products are tested and/or evaluated on a periodic basis (typically annually). This ensures continued compliance with the requirements of the standard, and confirms that the manufacturer continues to operate in accordance with NSF's general and program specific certification policies.

The initial application fee is US\$500 but the total cost of certification³¹ is much greater than this since, before certification is obtained, the NSF must review the formulation and the toxicity of components and impurities in order to evaluate the potential impacts on water quality as required in the NSF standards. This service, and the chemical analytical work in NSF laboratories, is performed on a fee for service basis invoiced to the applicant.

NSF Listings are published every six months and distributed at no charge to over 6,500 users, regulators, consulting engineers and purchasing agents. The Listings are updated daily and are available online.

7.5.1 Chemical Analysis and Normalisation

The standard requires a formulation review and chemical analysis of the material or chemical, this is usually performed by NSF International. Contaminants identified in the analysis are normalised to "at-the-tap" concentrations using the following equations:

For Non Polymers:

$$\frac{\text{mg contaminant}}{\text{L solution}} \times \frac{\text{L analysis solution}}{\text{g product}} \times \frac{\text{mg product}}{\text{L drinking water}} = \frac{\text{mg contaminant}}{\text{L drinking water}}$$

[analysis solution] [lab preparation solution] [maximum use level] [at-the-tap-exposure]

For Polymers:

$$\frac{\mu\text{g contaminant}}{\text{g polymer}} \times \frac{1\text{g}}{1000\text{ mg}} \times \frac{\text{mg product}}{\text{L drinking water}} = \frac{\mu\text{g contaminant}}{\text{L drinking water}}$$

[analysis solution] [maximum use level] [at-the-tap-exposure]

7.5.2 Determination of a SPAC

The Single Product Allowable Concentration (SPAC) is defined as "the maximum concentration of a contaminant in drinking water that a single product is allowed to contribute". To calculate the SPAC an estimate of the number of potential sources of the substances from all products in the drinking water treatment and distribution system, is required. In the absence of specific data on the number of sources for the contaminant, a default value of 10% percent of the MCL, or Maximum Acceptable Concentration (MAC) is used.

³¹ See also the Chapter on South Africa

The MAC is directly equivalent to a drinking water guideline level such as those contained in the *Australian Drinking Water Guidelines* (NHMRC 1996). Annex A of the Standard details procedures and decision criteria in the derivation of a MAC.

There are two methods for calculating a SPAC:

1. For contaminants with a MAC determined by a regulatory authority, and for unregulated contaminants where a quantitative risk assessment is required, the SPAC is determined by:

$$\text{SPAC (mg/l)} = \frac{\text{MCL or MAC (mg/l)}}{\text{Estimated number of sources in the DW treatment and distribution system}}$$

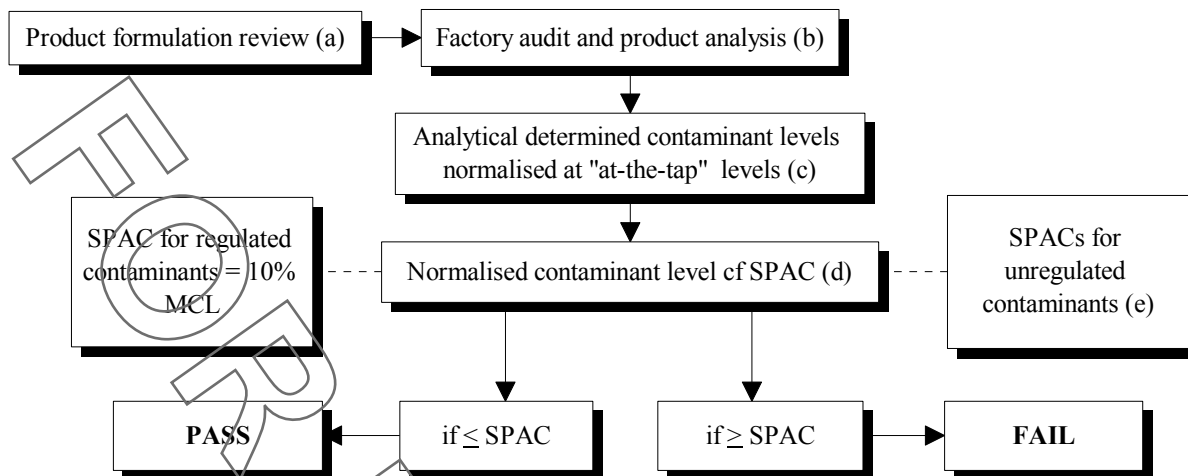
2. For substances which have undergone a qualitative risk assessment³² the:

$$\text{SPAC} = \text{MAC}$$

The standard also addresses the scientific rationale and procedures for determining Short Term Exposure Levels and for the use of data for structurally similar compounds.

³² Qualitative risk assessment applies where only genetic toxicity testing has been carried out and the “weight of evidence” review concludes that the substance (chemical constituent or impurity) is not a genotoxic hazard at 10 µg/l or less, or following genetic plus subchronic toxicity testing the “weight of evidence” review concludes that the substance is not a toxicological hazard at 50 µg/l.

Figure 7.3: ANSI/NSF 60 Evaluation Process



Notes for Figure 7.3

- a. NSF or a third party certifier first reviews the product/material formulation and other information submitted by a manufacturer to determine all potential contaminants that may be added to drinking water.
- b. A factory audit is scheduled and performed by the third party certifier. During the audit, formulations and suppliers are verified, QA/QC records are audited, and the product/material is sampled for analysis by the third party certifier. The sampled product/material is tested according to the protocols outlined in each of the NSF/AWWA standards.
- c. Contaminants identified in the analysis are normalised to “at-the-tap” concentrations using equations as presented in section 7.5.1
- d. The Single Product Allowable Concentration (SPAC) includes contribution of a substance/contaminant to potable water that may arise from multiple products or materials used in the treatment and distribution system, not just the chemical product brand being evaluated at the time. Procedures for the calculation of the SPAC are reported in Section 7.6.2. Basically the SPAC is the MAC (mg/L) divided by the estimated number of potential sources of the substance from all products in the drinking water treatment and distribution system. A default of MAC x 0.1 applies if the number of sources is unknown.
- e. For substances which have undergone a qualitative risk assessment the SPAC = MAC. The Standard (Annex A) details procedures and decision criteria in the derivation of a MAC. A summary of these procedures is presented in Figure 7.4 and section 7.6.2.

Table 7.1: Contents of ANSI/NSF Standard 60 Drinking Water Treatment Chemicals – Health Effects

Part 1-2	<p>Purpose, Scope and Definitions The standard sets minimum health effects requirements for chemicals and contained impurities that are directly added to drinking water regardless of whether they are present/measurable in the tap water. It does not specify aesthetic requirements. Byproduct contaminants produced by reaction of treatment chemicals with other constituents of the water to be treated are not covered by the standard.</p>
Part 3	<p>General Requirements This part specifies evaluation procedures. The central tenant of the evaluation is health based risk assessment. Detail is presented in Annex A and Annex B of the standard.</p>
Part 4-8	<p>Defines generic categories of chemicals and individual chemicals within each category, sampling and analytical procedures plus normalised concentration calculations are specified within each chemical category Generic subject listings in parts 4-8 4. Coagulation and Flocculation chemicals 5. Corrosion and Scale Control, softening, precipitation and pH adjustment chemicals 6. Disinfection and oxidation chemicals 7. Miscellaneous treatment applications 8. Miscellaneous water supply products</p>
Annexes	
A	<p>Toxicology Review and Evaluation Procedures This defines the toxicological review and evaluation procedures that are the backbone of the Standard. Annex A defines procedures to derive TAC (total allowable concentration) and SPAC. Refer Figure 7.3 and text for further details.</p>
B	<p>Sampling, Preparation and Analysis of Samples (normative) Specifies procedures for collection and preparation of samples plus analysis procedures.</p>
C	<p>Evaluation of microbiological growth potential Provides a protocol for determining a product's potential to support microbiological growth.</p>
D	<p>Normative drinking water criteria Lists drinking water criteria ('at-tap') that are used as normative evaluation criteria for determination of product compliance with the Standard. There are four tables intended to be used in a hierarchical approach: 1. Consensus US EPA / Health Canada drinking water criteria for contaminants evaluated by these two agencies 2. Non regulated (drinking water) contaminants for which criteria have been developed according to toxicity data requirements of Annex A and have been externally peer-reviewed 3. Non regulatory US EPA guidance values that have been reviewed and satisfy Annex A toxicity data requirements 4. A list of chemicals that are evaluated using a threshold of evaluation</p>
E	<p>Informational drinking water criteria These are drinking water criteria which have not been peer reviewed. There are 2 tables: E1- Drinking water criteria for unregulated contaminants that have been identified in extracts of materials covered by this Standard and table E2- Threshold of evaluation chemicals having data sets from which specific TAC/SPAC values could possibly be set using Annex A.</p>
F	<p>Chemical Product Index An index of chemicals and reference to relevant sections of the Standard</p>

7.5.3 Toxicological Evaluation Procedures – Third Party Risk Assessments

According to ANSI/NSF 60, published and peer reviewed chemical risk assessments that have been conducted for drinking water applications or for environmental regulation can be used for establishing a maximum allowable concentration. A hierarchy of acceptable published risk assessments and attending drinking water guidelines has been established:

- a. Consensus MCLs (Maximum Contaminant Levels) developed by the US EPA and Health Canada. There are 99 consensus MCLs (presented in Annex D Table D1 of Standard 60). If a consensus MCL is available no further deliberation to source a drinking water guideline is required; and
- b. If neither a US EPA nor Health Canada MCL is available, then other relevant regulatory risk assessments can be considered, but an evaluation of its appropriateness to drinking water is required. The criteria for appropriateness are found in Annex A of the Standard. The relevant regulatory bodies mentioned by the Standard include (in hierarchical order):
 - WHO drinking water guidelines;
 - International Programme on Chemical Safety;
 - UK Drinking Water Inspectorate;
 - KIWA;
 - US EPA IRIS;
 - US EPA Health Advisory;
 - US Food and Drug Administration;
 - US State Environmental or Health Authorities;
 - overseas National or International;
 - private corporations;
 - industry associations; and/or
 - individuals reviews.

7.5.4 Risk Assessment

When updating or creating a new chemical/contaminant risk assessment, the Standard provides guidance on minimum data requirements (refer also Figure 7.4). Basically, all available data on all aspects of toxicity are required to be included in the review eg. acute toxicity (1-14 day exposure), subacute, subchronic, chronic, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, genetic toxicity and human data.

If toxicity testing of the substance is required, the Standard requires it be conducted according to GLP and in accordance with the latest protocols adopted by OECD, US EPA or US FDA. The standard provides for qualitative or quantitative risk assessments to be undertaken depending on the toxicological test results and the calculated normalised concentration of chemical/contaminant at the tap. “When available toxicity data are insufficient to perform the qualitative or quantitative risk assessment, or when toxicity data are available, but the normalised contaminant concentration does not exceed the applicable threshold of evaluation value, a threshold of evaluation shall be determined for the substance according to procedures in Annex A of the Standard if applicable”.

Qualitative risk assessment is limited to situations where:

- the weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the substance is not a hazard at 10 µg/L or less in the drinking water; or;
- the weight of evidence review of the required genotoxicity studies, a repeat-dose study of less than 90 days duration and all other relevant data concludes that the substance is not a human health hazard at exposures of 50 µg/L or less; or
- A “Threshold of Evaluation” applies if the concentration of the contaminant at tap is less than 3 µg/L (normalised static³³ system), 0.3 µg/L (normalised flowing system) or 10 µg/L ‘acute’ conditions.

Quantitative risk assessment methodologies are specified in Annex A of the Standard 60. These include:

For non-carcinogenic endpoints, either of the following procedures is required:

- (a) *NOAEL/LOAEL procedure; or benchmark dose level procedure* which involves identification of the critical toxicity study and derivation of a reference dose (RfD) based on US EPA guidance (US EPA 1993):

$$\text{RfD (mg/kg bw/d)} = \text{NOAEL(LOAEL)/UF} \times \text{number of days dosed per week/7 days}$$

Where NOAEL = No observed adverse effect level (mg/kg bw/d)
LOAEL = Lowest observed adverse effect level (mg/kg bw/d)
UF = Uncertainty factor (total)

An uncertainty factor of between 1 and 10 (default 10) can be selected for interspecies variability, intraspecies variability, lack of a chronic study, use of LOAEL rather than NOAEL, and inadequacies in the dataset.

From this, the Total Allowable Concentration (TAC) is calculated according to the following equation:

$$\text{TAC (mg/L)} = \frac{[\text{RfD} \times \text{BW}] - [\text{total contribution of other sources (mg/kg)}]}{\text{DWI (L/day)}}$$

Where BW = Body weight of individual to be protected
(10 kg for a child, 70 kg for an adult)
DWI = Drinking water intake (generally 1 L/d for child, 2 L/d for adult)

In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% is used.

- (b) *Benchmark Dose Level (BMDL)*:

This process utilises the lower confidence limit on the dose that produces a specified magnitude of change (10%) in a specified adverse response (BMD₁₀) rather than the NOAEL

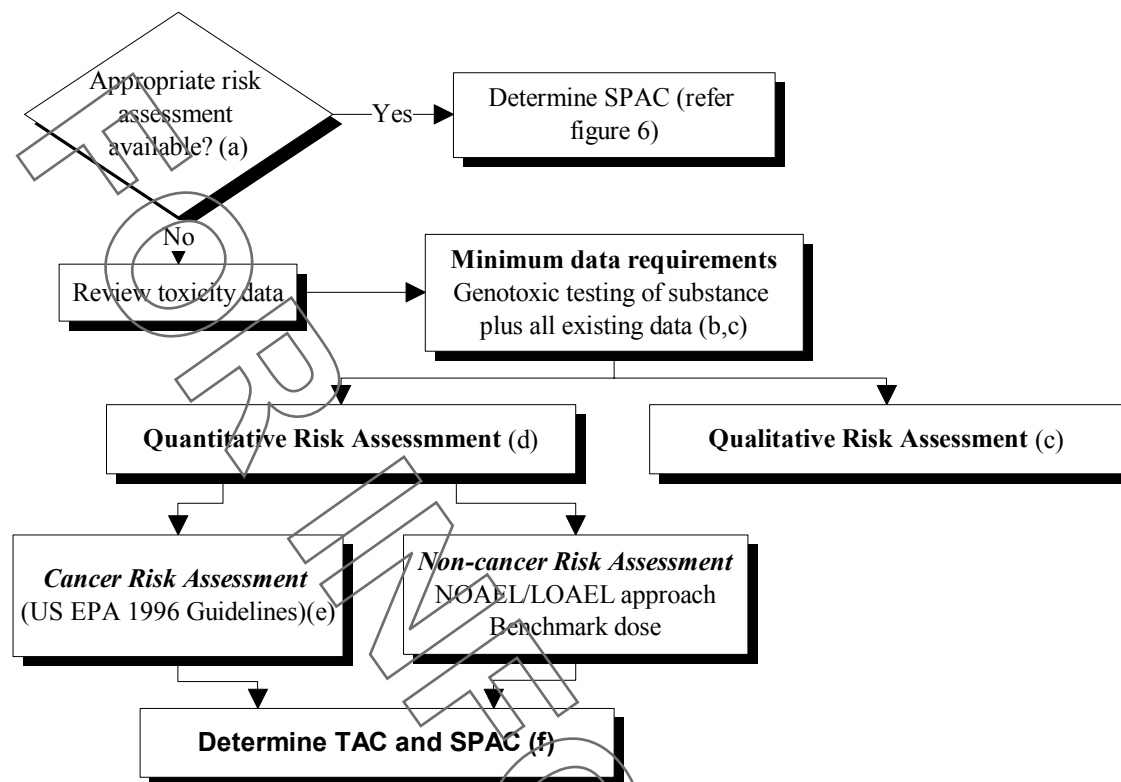
³³ Static and flowing conditions are not defined by the ANSI/NSF Standard 60.

or LOAEL. Once the BMD is derived, the procedure for determining the MAC is the same as for the NOAEL/LOAEL procedure.

- For carcinogenic endpoints, US EPA Cancer Risk Assessment Guidelines (draft, 1996) are utilised. The Standard requires dose response assessment for known human carcinogens and probable human carcinogens. It requires extrapolation of the dose response curve to account for low human exposure.

For quantitative risk assessment the minimum dataset includes the genetic toxicity testing required for qualitative risk assessment plus a relevant GLP subchronic toxicity study conducted to OECD, US FDA or US EPA test guidelines.

Figure 7.4: Summary of ANSI/NSF Standard 60 Toxicological Evaluation Procedures



- a. Only published and peer reviewed risk assessments are used to establish MACs. Refer to section 4.6.1. It is unclear whether the same standard is applied to qualitative risk assessment.
- b. The minimum data requirements specified in Annex A of NSF 60 are dependent on quality of existing data and normalised concentrations of chemical/impurity. However the process for determining the minimum data requirements is complex and not easily followed in the Standard. The minimum toxicity data required for a risk assessment appears to be genetic toxicity testing. Tests specified by the Standard include: A gene mutation assay such as the bacterial reverse mutation assay with and without exogenous metabolic activation (*Salmonella typhimurium* or *Escherichia coli*); and, an *in vitro* chromosomal aberration assay. Metaphase analysis in mammalian cells with and without exogenous metabolic activation. A positive result in either assay necessitates appropriate *in vivo* genetic toxicity testing.
- c. Decision on whether qualitative risk assessment is required is dependent on concentration of the chemical in drinking water and a weight of evidence assessment of hazard based on genetic and/or subchronic toxicity testing. Quantitative risk assessment is required for all other situations. Refer to section 4.6.4.
- d. The methodologies for quantitative risk assessment are summarised in section 4.6.4.
- e. For carcinogenic endpoints, USEPA Cancer Risk Assessment Guidelines (draft 1996) are utilised. The Standard requires dose response assessment for known human carcinogens and probable human carcinogens. It requires extrapolation of the dose response curve to account for low human exposure.
- f. For regulated and unregulated contaminants the SPAC is the TAC (Total Allowable Concentration) (mg/l) divided by the estimated number of drinking water sources for the contaminant. For substances which have undergone a qualitative risk assessment only the SPAC = MAC.

7.6 American Water Works Association (AWWA) standards

Since 1908, the American Water Works Association (AWWA) has developed consensus standards for drinking water treatment chemicals (DWTC). Table 7.2 lists the AWWA standards for drinking water treatment chemicals. AWWA standards provide minimum requirements for drinking water treatment chemicals. For each compound, these standards describe a chemical's origin, physical properties and how it is used in water treatment. The standards do not assess toxicological aspects and do not recommend or specify allowable impurity levels in drinking water. The standards apply to chemicals generically used to treat water and not to the finished water. Each standard stipulates quality and concentration requirements for the generic DWTC and recommends various physical and/or analytical tests to be used to verify product strength, activity and for determination of presence of contamination in propriety brands of the DWTC. The recommended testing includes verifying the physical appearance and odour for all treatment chemicals except compressed gases/liquids (Casale & LeChevallier, 2000).

Compliance with the AWWA standards is voluntary. However, the standards can and have been made mandatory by utilities and regulatory agencies.

In developing or approving a standard, AWWA does not test any products (AWWA 2001). The AWWA Standards do state that certification should be sought to ANSI/NSF Standard 60. For instance, AWWA Standard B501-98 (AWWA 1998) for sodium hydroxide (Caustic Soda) states:

Sodium hydroxide is a direct additive used in the treatment of potable water. This material should be certified as suitable for contact with or treatment of drinking water by an accredited certification organisation in accordance with ANSI/NSF Standard 60, Drinking Water Treatment Chemicals—Health Effects. Evaluation shall be accomplished in accordance with requirements that are no less restrictive than those listed in ANSI/NSF Standard 60. Certification shall be accomplished by a certification organisation accredited by the American National Standards Institute.

AWWA standards are consensus standards; they are developed by volunteer committees whose members are representatives of all segments of the drinking water community. The committee members must reach a consensus before a standard is sent to the AWWA Standards Council and the Executive Committee for review. The AWWA Board of Directors gives final approval. The drinking water treatment chemical standards are approved by the ANSI.

Table 7.2: List of Drinking Water Treatment Chemicals with an AWWA Standard

1. Coagulation	<p>Ferrous sulfate Aluminium sulfate - liquid, ground, or lump Liquid sodium silicate Sodium aluminate Ferric sulfate Liquid ferric chloride Liquid polyaluminium chloride Poly diallyldimethylammonium chloride EPI-DMA Polyamines Polyacrylamides</p>
2. Disinfection Chemicals	<p>Hypochlorites Chlorine liquid Ammonium sulfate Addendum to Ammonium Sulfate Sodium chlorite</p>
3. Filtration	<p>Filtering materials Precoat filter media</p>
4. Prophylaxis	<p>Sodium fluoride Sodium fluorosilicate Fluorosilicic acid</p>
5. Scale and Corrosion Control	<p>Sodium polyphosphate, glassy (Sodium Hexametaphosphate) Sodium hydroxide Sodium tripolyphosphate Monosodium phosphate anhydrous Disodium phosphate anhydrous Carbon dioxide Potassium hydroxide Sulfur dioxide Calcium chloride</p>
6. Softening	<p>Sodium chloride Soda Ash Quicklime and Hydrated lime</p>
7. Taste and Odour Control	<p>Powdered activated carbon Sodium metabisulfite Copper sulfate Potassium permanganate Granular activated carbon</p>

8. The Netherlands Processes for Evaluating Materials in Contact with Drinking Water

8.1 Overview and Regulatory Background

A schematic overview of the Dutch process is shown in Figure 8.1. The overarching legislation is the EU Drinking Water Directive (EU 1994)³⁴, but there is also the Drinking Water Decree³⁵ (DWD) and the Dutch Water Works Decree³⁶. The authority responsible for drinking water quality in the Netherlands is the Chief Inspector of Public Health and Environmental Protection of the Ministry of Housing, Spatial Planning and the Environment (VROM). The water works must meet their statutory obligations to supply good quality drinking water according to the EU Directive for chemical contaminants in finished water. To enable this, the Dutch Government, via VROM, in collaboration with the Dutch Water Works Association, has established a central evaluation system for materials used in the preparation of drinking water. The Chief Inspector has established criteria known as “The Assessment on Toxicological Aspects (ATA)”, against which the evaluation must be made. Kiwa³⁷ administer the regulations and coordinate the health aspects of the chemical product evaluation. The regulations are binding on Kiwa and these criteria are often referenced as the ‘Kiwa-Regulations for the ATA Product Certificate’ (Kiwa 1994).

In order to establish the criteria (regulations) the Chief Inspectorate is advised by the Committee for Health Aspects for Chemicals and Materials for Drinking Water Supplies (CGCMD). This committee is further assisted by the Sub-Committee Toxicity (W4).

- The evaluation procedure for certification consists of three parts:
- An assessment of the manufacturing process³⁸,
- The toxicological evaluation of the product (see figure 8.2); and
- An evaluation of the internal quality system of the manufacturer³⁹.

³⁴ The EU Drinking Water Directive [80/778/EEC as amended in COM (94) 612-final] is a legal framework for member EU States to address failures of water quality. It specifies a limited number of parameters for drinking water quality and in relation to substances used in the preparation of drinking water merely states that impurities associated with such substances do not remain in the water at concentrations higher than is necessary for the intended purpose of product use, and do not reduce the protection of human health provided for in the Drinking Water Directive.

³⁵ The Drinking Water Decree is a document similar to the Australian Drinking Water Guidelines and provides specific national guidance to water works in the Netherlands regarding the allowed range of organic and inorganic contaminants in drinking water.

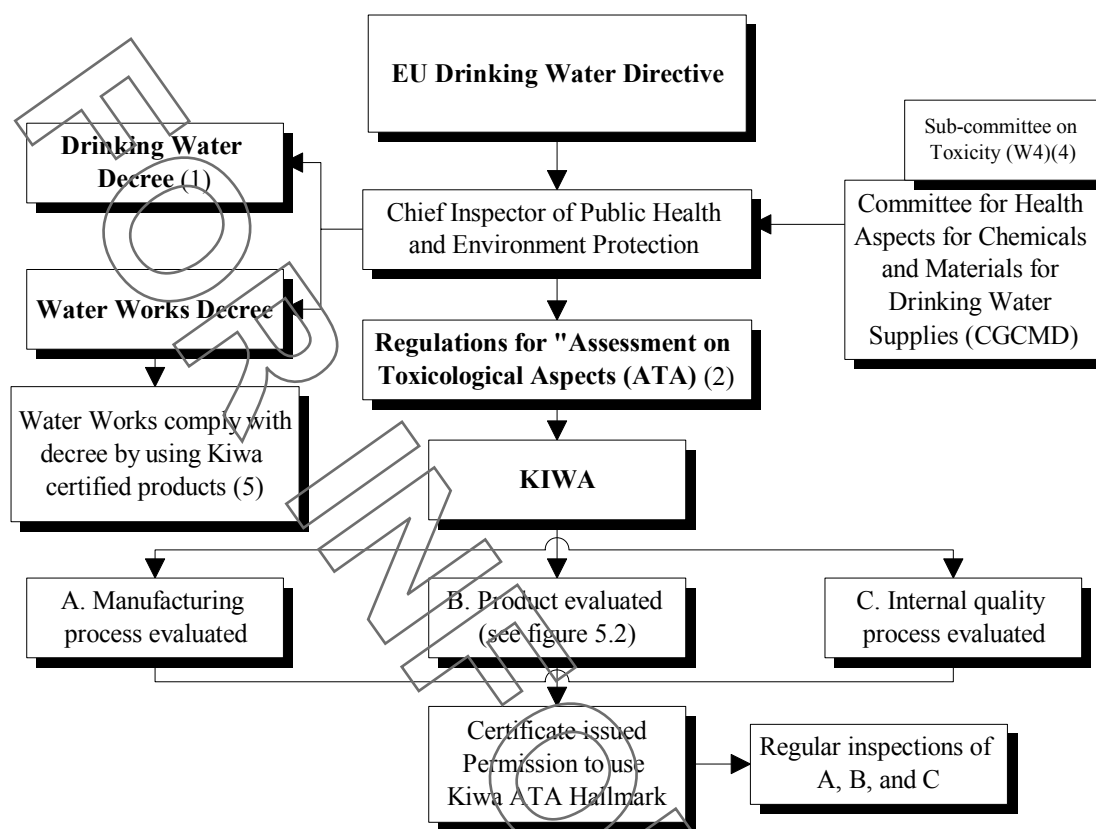
³⁶ A description of the content of this Decree was not available for review.

³⁷ Kiwa is an independent not-for-profit organisation established in 1948 and is involved in a range of certification programs, inspection services, research and consultancy, management consultancy and quality accreditation programs. It conducts these activities in various market sectors: drinking water industry, waste processing, public utilities, soil protection, road and hydraulic engineering, commercial and industrial building industry, public health, agriculture, petrochemical industry etc. It offers services in the Netherlands, Belgium, Germany and Italy.

³⁸ Kiwa visits the manufacturers works to ascertain whether the production process conforms with the Kiwa criteria, any samples deemed appropriate may be taken. In addition aspects such as internal transport, storage, and quality of raw materials, semi-manufactures and end products as well as of rejected products, products to be repaired and the marketing of products are assessed.

³⁹ This usually covers such things as whether there is a quality system and if an executive is responsible for it, measuring and research facilities, inspection methods, recording filing & archiving of measurements, procedures for corrective actions, procedures for dealing with complaints, whether off-specification product would be identified before leaving the gate etc. In short this appears to be an audit of the QA & QC systems of the manufacturer.

Figure 8.1 Overview of regulatory framework and evaluation bodies for the approval of materials in contact with drinking water in the Netherlands



- ¹ The Drinking Water Decree is the equivalent of the Australian Drinking Water Guidelines.
- ² Kiwa administers the regulations and coordinates the health evaluation on behalf of the Chief Inspector, hence they are often referred to as the “Kiwa-Regulations for the ATA Product Certificate”.
- ³ Kiwa is an independent, not for profit organisation (See also footnote 37 in main text) and conducts phases A, B, & C. It also coordinates and participates in the toxicological/health risk assessment performed by CGCMD & W4
- ⁴ W4 has experts from industry, Kiwa and the Authority (VROM).
- ⁵ Although a Kiwa-ATA certificate is not a mandatory requirement for products in contact with drinking water most water works do not accept foreign approved products, or products without Kiwa certification (WHO, 2000).

The output of the evaluation is the issuance of a certificate used as proof by the manufacturer that:

- the relevant product meets the criteria established by VROM; and
- the quality system and manufacturing process comply with the requirements.

In addition, the manufacturer is obliged to mark the certified products with the Kiwa ATA hallmark in a manner agreed with Kiwa. After the evaluation, the manufacturer enters into a contract that obliges the manufacturer to notify Kiwa of any changes in the composition of certified products and/or their applications. There is also an agreement that provides for periodic inspections of the manufacturing process, quality system and product analysis

⁴⁰ Analysis of raw materials and product for initial and continuing evaluation is performed at Kiwa laboratories on samples obtained under Kiwa personnel supervision. The contract also makes provisions for not changing the product marking

Kiwa publishes an annual list of approved products (the positive list) which aids water authorities in choosing appropriate products for use and manufacturers in choosing components for materials to come into contact with drinking water.

8.2 Relationship with European Standards

No discussion was located regarding interfacing with harmonisation schemes in Europe or the use of EN standards in the Netherlands. WHO (2000) makes the observation that water suppliers in the Netherlands generally do not accept foreign certified products.

8.3 Product Evaluation Process

The system for evaluating drinking water treatment chemicals in the Netherlands is broadly similar to the US process in that legislation/regulations specify the end quality of the treated water and that water treatment chemicals must not compromise water quality. As in the USA (with NSF), an independent third party (Kiwa) administers the evaluation process (Figure 8.1). There is further similarity in that Kiwa uses a positive list⁴¹ (Kiwa 1994a) to aid evaluation, which functions in a similar manner to the specific standards of ANSI/AWWA. However, when the positive list is not applicable, the Kiwa evaluation is performed in conjunction with regulatory appointed expert committees who evaluate the toxicological data package (Figure 8.2 and footnotes therein). In this aspect, the Netherlands process is similar to that of the UK where the CPP Committee conducts a toxicological and health risk assessment, and to the NSF system where evaluation is dependent on health risk assessment and a normalisation procedure of the impurity in the treatment chemical.

- The use of the positive list is meant to speed up the assessment process, and for plastic materials it probably performs this function well. However since there are only eleven drinking water treatment chemicals on the list it is difficult to envisage such an advantage in the assessment of chemicals⁴².
- It is unclear how the Netherlands positive list gains additional listings of generic chemicals in common use for the treatment of drinking water⁴³.

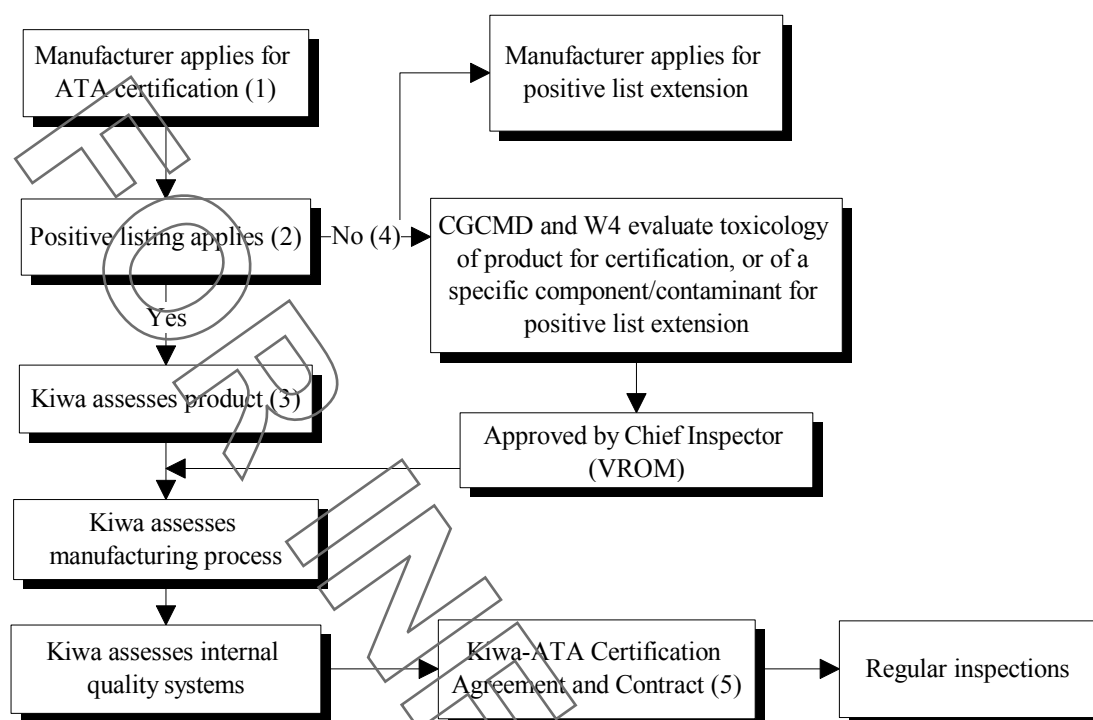
with the Kiwa hallmark without consent from Kiwa, toll manufacturing of the certified product, measures to be taken in the event of non-conformities on inspection, and termination of the ATA certificate.

⁴¹ The list is reasonably comprehensive for materials that may leach from plastics. For polybutene-1, polyethylene, polypropylene, PVC and rubber products there are extensive lists of catalysts, emulsifiers, antioxidants, blowing agents, lubricants, anti-statics, stabilizers, dyes and pigments (to be published) and other additives used in plastic manufacture. These are listed as an allowed amount in leachate from the standard test (i.e. mg additive/l). In contrast there are only 11 treatment chemicals on the positive list; these have limits (mg/kg treatment chemical) for heavy metals and in some cases primary amines that may be allowed in the treatment chemical. The list also specifies the details for a number of analytical techniques that must be used.

⁴² Three of these 11 are calcium salts and 4 are ferric/ferrous salts. Many more chemicals than these 11 must have been in use for many years in the treatment of drinking water in the Netherlands. It is difficult to envisage that different brands of all these 'in use' chemicals would have gone through the toxicology arm of the evaluation procedure (see fig 2). Nevertheless Toxikos has been unable to glean any information regarding 'grand fathering', 'GRAS' or 'long term use status' for chemicals in the Netherlands. Note the UK has provision for 'long term use status' of chemicals to allow their continued use without formal evaluation.

⁴³ The logical process is either for the State to conduct the appraisal for establishing the standards for, and listing of, a generic chemical e.g. alum or activated charcoal, or a chemical/industry association sponsors the process, however evidence for neither of these was found.

Figure 8.2 Summary of the ‘Kiwa-ATA’ Evaluation Procedure for Chemicals and Materials used in Preparation or Transport of Drinking Water.



- 1 Kiwa provide application forms and general guidance on the type of information required.
- 2 The positive list is published by the Chief Inspectorate through Kiwa (1994b). It consists of an allowed concentration of contaminants in chemicals, or an allowed leaching rate of specified contaminant from materials, for a limited number of products. By specifying allowed levels of contaminants the positive list appears to function in a similar way to the American ANSI/AWWA Standards for Drinking Water Treatment Chemicals (ANSI/AWWA 2001). However the latter are written up as individual standards each of which has to be purchased at a current cost of US\$35. The positive list is provided free.
3. It appears that Kiwa requires that supplier pay for the contaminant analyses of chemical products and the leachate tests of materials performed in Kiwa laboratories. These independent results are then compared to the positive list. If the tests pass then the process continues.
4. If a contaminant in leachate or treatment chemical is not the positive list then the manufacturer may apply to have the list extended or to have the product evaluated by CGCMD. In either case, toxicological data is required (see section 5.4 in main text).
5. There exist regulations for the resolution of disputes should, at any stage the manufacturer disagree with a decision of Kiwa (Kiwa, 2001).

8.4 Data requirements for evaluation

Evaluation of the proposed DWTC requires standard information about the product and manufacturer⁴⁴ and information to assist the evaluation of manufacturing process and the producers internal quality system. For contaminants or chemicals that are not on the positive list, toxicological information is also required. The toxicity data to be supplied by the applicant for both materials and chemicals is determined after consultation with the secretariat of the W4 committee of CGCMD.

⁴⁴ For example see the general section of table 2 in the UK chapter.

For materials: The minimum data set for the leached component not on the positive list is:

- Rat oral LD₅₀ with clinical signs ⁴⁵;
- Semi-chronic toxicity study (rat oral 90d, 3 dose groups) ⁴⁶; and
- Mutagenic potential. ⁴⁷

For chemicals: CGCMD consider that to evaluate the toxicological risk of chemicals applied directly to drinking water “an extensive testing programme like those used for food additives is in principle appropriate” ⁴⁸. However depending on the application, water dosage rates, final calculated concentrations in water, and other considerations, the evaluation may take place on a more limited data set. ⁴⁹

8.5 Principles of toxicological data evaluation:

The basic principles employed in data evaluation are those of WHO (1987). The no effect level (LEL) ⁵⁰ is used to derive the maximum tolerable concentration ⁵¹ (MTC) in water. Since intake of the contaminant may come from sources other than drinking water the CGCMD stipulate that the contribution made by drinking water must not exceed 10% of the maximum tolerable daily intake (TDI) for the contaminant. In addition, the following two caveats are applied:

- Limits laid down in the Dutch DWD shall not be exceeded, and
- Exposure of people to toxic chemicals, even in concentrations less than those regarded as the maximum tolerable level shall be avoided as far as possible.

8.6 Costs and Timing

Kiwa determines the cost of certification depending on the work involved. It normally gives the manufacturer an indicative quote and provides periodic ‘preliminary’ invoices. At the end of the job these are grossed up and a total account provided to the client. If the producer fails to pay the pre-certification costs on time, Kiwa has the right to suspend the application procedure and/or the ATA certificate.

- The manufacturer pays all costs incurred by Kiwa during the evaluation at a rate determined by Kiwa, in large part Kiwa also determine the scope of work for the evaluation.

⁴⁵ Presumably any of the OECD agreed alternatives to the traditional LD₅₀ test can be provided.

⁴⁶ Low surface contact &/or low migration &/or QSAR considerations may support submission of a 4-week study in lieu of a 90 day study .

⁴⁷ A reverse bacterial point mutation assay plus two tests in eukaryotic cells (either both point mutation or 1 point mutation and 1 chromosomal aberration). A choice of 4 different assays systems is provided.

⁴⁸ In addition to the minimum requirements stipulated for materials; chronic, reproduction & teratogenic tests are needed together with kinetic & biotransformation data.

⁴⁹ If the extensive data set is required it is not surprising the positive list contains only 11 chemicals. It is noted however that the calculation of a MTC uses a semi-chronic NOAEL.

⁵⁰ The CGCMD use NEL interchangeably with NOEL, NAEL & NOAEL.

⁵¹ The MTC is calculated by applying a safety factor (SF) of 100 to the NEL from semi-chronic testing, assuming 60 kg bw, consumption of 2 l water per day and 10% allocation of TDI to water.

$$\text{MTC (mg/l)} = \frac{\text{NEL (mg/kg/d)} \times 60\text{kg}}{\text{SF (100)} \times 2\text{l/d}} = \frac{\text{NEL} \times 3}{\text{SF}}$$

- The manufacturer also pays the costs in connection with preparing and maintaining the certification scheme and for carrying out inspections. In addition, the manufacturer also pays a fee for the right to use the ATA certificate.

Kiwa undertakes to initiate the evaluation within one month of receiving an application and to notify the applicant of the outcome within one month of completing the evaluation. Toxikos was unable to get estimates for the average time for completion of an evaluation. It appears to be variable but can be quite long (eg. > 9 –12 months).

9. Development of a Scheme for Water Treatment Chemicals in the Republic of South Africa

At present no regulatory mechanism exists in the Republic of South Africa (RSA) for the control of drinking water chemicals. There are some SABS⁵² standard specifications to control the quality of innocuous chemicals (eg. lime, bentonite etc) when these chemicals are used to treat water, but the majority of chemicals in use in RSA are not subject to either regulatory control or evaluation prior to use. Between 1986 and 1994 the Department of Health⁵³ evaluated and approved drinking water treatment chemicals on an ad hoc basis using a system that had no legal basis. The supplier provided to RSA Department of Health approval or certification from a recognised world health body, or evidence that the product met US EPA or other international standards. The Department of Health then issued a certificate that allowed the product to be considered for use by water providers.

The current National Department of Health, via a consultative process, is keen to establish⁵⁴ a legally compliant registration and approval system for drinking water chemicals and a number of workshops were conducted in 1999-2000. Confidential draft legislation has been apparently developed as a result of this process (Workshop 1999, WST 2000a, WST 2000b, Barnes & Makwela 2000).

During the consultation process, water providers, industry and various government departments fully supported the need for the development of an approval scheme. Requirements were that the registration system should be:

- all encompassing – ie. legally binding for all chemicals and materials;
- chemically unbiased – the system should not result in favour to one chemical over another;
- economically unbiased – should not favour large companies over small, nor international over local;
- reduce human health risks – the evaluation process should be risk based; and
- stakeholder driven – registration procedure drafted in consultation with stakeholders.

Although the draft legislation could not be obtained, it is believed that the registration scheme contains the following elements:

- The manufacturer/supplier is responsible for obtaining registration and the user must/should use only registered products⁵⁵;
- An application fee and all relevant documentation must accompany application on the prescribed form;
- An Evaluation Committee will be established which will make recommendations to the Director General of Health based solely on potential health effects of the chemical to

⁵² South African Bureau of Standards

⁵³ In the period in question the department of Health was known as Department of National Health and Population Development.

⁵⁴ Under section 37(c) of the Health Act 1977, and according to The Bill of Rights (i.e. everyone's right to have access to safe drinking water).

⁵⁵ For chemicals the registration will be based on chemical product as added to water.

domestic water users, and evaluations will be made on the basis of data from an accredited laboratory⁵⁶;

- For registration of an existing product also registered overseas new toxicological data need not be generated⁵⁷. However, the Committee can request the applicant to perform the toxicological tests at a local, accredited institution; and
- If any of the submitted data is questionable, the Department of Health reserves the right to carry out an independent toxicological evaluation of the product at the applicant's expense.

It appears that most of the detail for the operation and technical evaluation aspects of the proposed registration scheme have not been developed and it may be some time before the scheme is available.

⁵⁶ During consultation a survey of facilities able to undertake toxicology tests, and of what tests were available was to be undertaken. The results were not available at the time of writing this report. It is the understanding of Toxikos (to be confirmed) that there are no GLP accredited toxicology testing facilities in RSA.

⁵⁷ It is not clear how, or if existing evaluations/certifications will be taken into account during evaluation however we assume the complete data package of existing data previously evaluated by the overseas body will need to be submitted to the committee. However during the consultation phase the water providers and suppliers strongly advocated the US NSF and AWWA processes be tapped. At the moment there is only one RSA manufacturer of drinking water treatment chemicals that has its products (2x) accredited by NSF. The accreditation took 9 months and about R500,000 (~A\$125,000 for the time) (WST 2000b). On face value therefore it would seem that adoption of the NSF process in a formal way would violate the economic and chemical anti-bias provisions of the scheme, and for many of the producers of DWTC in RSA would be cost prohibitive.

Acronyms & Abbreviations

ADI	Acceptable daily intake
ANSI	American National Standards Institute
ASDWA	Association of State Drinking Water Administrators
ATA	Assessment of Toxicological Aspects
AWWA	American Water Works Association
BMD ₁₀	Benchmark dose for 10% effect incidence at lower confidence limit on dose
BS: EN	British/European Standards
CEN	European Standards Institution
CGCMD	Committee for Health Aspects for Chemicals and Materials for Drinking Water Supplies
CPP	UK Committee on Products and Processes for Use in Public Water Supply
CSA	Canadian Standards Association
DETR	Department of Environment Transport and Regions
DWD	Drinking Water Decree
DWI	Drinking Water Inspectorate
DWTC	Drinking water treatment chemical
DWTCWP	Drinking Water Treatment Chemical Working Party (NHMRC)
GLP	Good laboratory Practice
ISO	International Standards Organisation
KIWA	Dutch independent not for profit organisation
LEL	Lowest effect level
LOAEL	Lowest observed adverse effect level
MCL	Maximum contaminant level
MD	Maximum dosage of the drinking water chemical
MOU	Memorandum of understanding
MTC	Maximum tolerated concentration
NHMRC	National Health and Medical Research Council (Australia)
NOAEL	No observed adverse effect level
NS	National drinking water standard
NSF	National Sanitation Foundation (US)
NZWWA	New Zealand Water and Waste Association
RfD	Reference dose
RMIC	Recommended maximum impurity content
RSA	Republic of South Africa
SABS	South African Bureau of Standards
SDWA	Safe Drinking Water Act
SDWR	Safe Drinking Water Regulations
SF	Safety factor
SMCL	Secondary maximum contaminant level
SPAC	Single product allowable concentration
TAC	Total allowable concentration
TDI	Tolerable daily intake
US EPA	United States Environmental Protection Agency
VROM	Public Health and Environmental Protection of the Ministry of Housing, Spatial Planning and the Environment, The Netherlands
WHO	World Health Organization

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