QMRA: its value for risk management

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Gertjan Medema
Kiwa Water Research, The Netherlands

Nicholas Ashbolt
University of New South Wales, Australia

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Acknowledgements

1 INTRODUCTION

The EU-project MicroRisk focused on Quantitative Microbial Risk Assessment (QMRA) as a scientific basis and tool to assess the microbial safety of drinking water supplies. This report describes how this risk assessment fits in the overall risk and quality management and how risk assessment can aid risk management. This report focuses on the water utility in its responsibility to manage drinking water safety and how the water supplier can make use of risk assessment. That does not imply that other stakeholders have no role in this risk-based approach. Each of these stakeholders is involved in the framework; the regulator is responsible for setting health-based targets for drinking water and enforcement of these targets and health authorities are responsible for control of the transmission of disease. The involvement of other stakeholders is briefly described in this report.

2 THE SAFE WATER FRAMEWORK

An international group of experts, assembled by the World Health Organization, discussed the approach to assess and manage the health risk of pathogenic micro-organisms in drinking water, recreational water and wastewater [Fewtrell & Bartram, 2001]. This group agreed that future guidelines for safe drinking water should integrate risk assessment and risk management into a single framework, the Safe Water Framework. The simplest form of the framework is given in Figure 1.
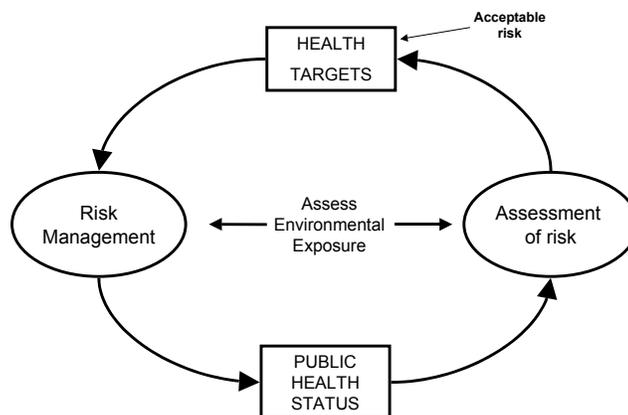
From: Fewtrell & Bartram, 2001. in Water Quality Guidelines, Standards and Health (WHO). IWA publishing.

Figure 1. Safe Water Framework for integrated risk assessment and risk management

The risk that is assessed and managed in this approach is human health risk. Given this document is addressing pathogens in drinking waters, the risk here is that consumers of drinking water will contract an infectious disease through use of the water. It is clearly an iterative cycle in which risk assessment is a basis for decision-making in risk management. The four steps of the cycle are described in the next paragraphs.

2.1 Health targets

Health targets are benchmarks for the water suppliers, set by the regulator as part of their health policy. Health targets for drinking water are traditionally strict, because of the large potential impact of contaminated tap water and the basic need for safe drinking water. This leads to the question of what level of health risk through drinking water could be tolerated, given the overall health status of the consumer population and the contribution of drinking water to the overall health risk of this population in relation to other routes of exposure, such as food, person-to-person or animal contact, recreational water etc. This is a question that typically needs answering on the level of the regulator, who can translate this information into a health target for drinking water, considering other factors such as relative contribution of drinking water transmitted disease to the overall health burden and the economic climate.

The health target is the level of a tolerable risk level for drinking water, which could be expressed as the tolerable risk of infection through drinking water (i.e. risk of infection $<10^{-4}$ per person per year [Regli *et al.*, 1999]) or the tolerable amount of disease burden (i.e. $< 10^{-6}$ disability adjusted life years (DALYs) per person per year [WHO GDWQ, 2004; Havelaar *et al.*, 2000]). The health target could be translated into water quality targets for pathogens (analogous to toxic chemicals). Rather than producing a standard and monitoring requirement for all pathogens that could be transmitted through drinking water, the use of a suite of "index pathogens" is advisable. Establishment of adequate control against this suite of pathogens should offer protection against the other known (and even unknown) pathogens.

It is emphasised that the health targets may differ due to health status situations. The judgement of what is a tolerable level of risk is a matter in which the society as a whole has a role to play; the decision on the cost-benefit is for each country to decide [WHO-Guidelines for Drinking Water Quality, 1993; 2004]. It is important that health-based targets, defined by the relevant health authority, are realistic under local operating conditions and are set to protect and improve public health. Health-based targets underpin development of Water Safety Plans [WHO GDWQ, 2004] and provide information with which to evaluate the adequacy of existing installations; and assist in identifying the level and type of inspection and appropriate analytical verifications. Further details on health-based targets are covered in Chapter 3 of the WHO GDWQ.

2.2 Risk management

In the EU, managing the safety of drinking water has been the core business of water supply companies for more than a century. Over this period, risk management has evolved into a culture, codes and specifications of good practice. In the last decades, quality management systems have been used in the water industry to formalise this. Currently, water suppliers in several EU-countries are using a HACCP (Hazard Analysis & Critical Control Points)-based approach for management of (microbiological and other) risks. The basic principles of HACCP are to understand the system and the hazards/hazardous events that may challenge the system, provide some ranking of their (health) priority and to ensure that adequate control measures are in place and functioning. HACCP-based systems typically focus on

good practice and even more specifically on ensuring that good practice is maintained at all times; it is a proactive system-wide stance, rather than one relying on 'failure' of final drinking water. It fits within existing quality management systems (i.e. ISO 9001 c.s.). HACCP is the well-established risk management tool that is used for food safety. The Codex Alimentarius (FAO/WHO code for food safety) defines HACCP as a system which identifies, evaluates and controls hazards which are significant for food safety [CODEX, 1997]. Although there are many aspects of drinking water that are similar to food, there are also differences. Based on experiences of water suppliers with HACCP, the control system has been refined and tailored for application in drinking water abstraction, treatment and distribution in WHO's Water Safety Plan. The Water Safety Plan is described in the Guidelines for Drinking Water Quality [WHO, 2004].

The principal components of the Water Safety Plan are:
System assessment to determine whether the water supply chain (from catchment through treatment to the point of consumption) as a whole can deliver water of a quality that meets the above targets.
Operational monitoring of the control measures in the supply chain which are of particular importance in securing drinking water safety.
Management plans documenting the system assessment and monitoring, and describing actions to be taken in normal operation and incident conditions, including upgrade and improvement of documentation and communication.

In the Water Safety Plan the risk assessment question: "Do we meet the health target?" is answered in the *System Assessment* and the risk management questions "How do we ensure and demonstrate that we always meet the target?" and "How do we respond to incidents?" are answered in the *Operational monitoring of control measures* and the *Management plans.*
For an overview of the Water Safety Plan and its context, the reader is referred to the WHO GDWQ and the Water Safety Plan guidance document [Davison *et al.,* 2005] that are published on the website of WHO Water, Sanitation and Health. The guidance document describes the steps of the risk management approach, illustrated with several case studies of drinking water utilities that have applied this system to their water supply systems. A Water Safety Plan Portal with information on water safety plans can be found on the same website.

2.3 Public Health Status

The primary objective of drinking water safety management is the adequate protection of public health. The incidence of waterborne illness in the population or the occurrence of waterborne outbreaks is a direct trigger for curative risk management. A more preventative incentive for assessing the water-related health risks and the installation of risk management is to demonstrate that the water supply is providing an adequate level of protection of public health.
The inclusion of health targets in national legislation and the risk management actions of water utilities should result in an improvement of the public health status. Without addressing this, it is impossible to see if the health targets set and risk management actions taken are effective and if money spent for improving water

supply results in a relevant health gain. This step in the circle is the place where the health risk of drinking water can be compared to other routes of exposure and to other health risks. It allows comparison (harmonisation) of the effort and resources put into the provision of safe drinking water and resources allocated to manage other health risks.

The risk assessment and management framework is a process that can and should be run in an iterative manner. This tiered approach fits well with the incremental nature of health decision making, the efficient use of scarce resources and the increase of information.

2.4 Risk assessment

Risk assessment is used to answer the question: "is my system able to produce and deliver drinking water that meets the health targets?". The risk assessment process requires quantitative information about the exposure of drinking water consumers to pathogens. This is provided by exposure assessment, one of the components of risk assessment. Quantitative information about pathogens in water sources, their removal by treatment and protection of the distribution network and drinking water consumption is collected and translated into an estimate of the exposure of consumers to pathogens through drinking water. To complete the risk assessment, the potential effect (the risk) of pathogen exposure is estimated through known dose-response models. As will be shown later, the exposure assessment also provides valuable information to aid risk management in the prioritisation of control measures.

An important question in risk management, especially in the European setting with an already high standard of drinking water safety, is "How far do we need to go with control measures?". This is an optimisation between the safety of and the costs for the consumer of drinking water.

Quantitative microbial risk assessment (QMRA) can provide an objective and scientific basis for risk management decisions. Water utilities can use QMRA to assess if they meet the health targets with their water treatment, storage and distribution systems. QMRA should also be used to provide information for setting critical limits in the Water Safety Plans to ensure good performance. Good performance can now be based on a quantitative assessment of the contribution of the Critical Point (such as a disinfection or filtration process) to the overall safety and the limits can be set to ensure that the multiple barrier chain of water collection, treatment and distribution as a whole does meets the desired health target.

Risk assessment and risk management should not be regarded as two separate steps in the harmonised framework. To answer the question: "Which control measures should be put in place to meet the target?", both the HACCP-based management system and quantitative risk assessment provide valuable input: for example, the hazardous events, the most important barriers in the system, the contribution of each of the barriers, target levels for control, the occurrence of weak elements in the chain, the quality of the available information etc.

3 THE EUROPEAN DIMENSION

The European Commissioner responsible for health and consumer safety stated "the Commission needs to find the balance between the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to human health and the environment. This balance should be science-based, proportionate, non-discriminatory, transparent and coherent and requires a structured decision-making process with detailed scientific, objective information within an overall framework of risk analysis." [Address by D. Byrne on the Precautionary Principle in the domain of human health and food safety. The Economist conference, Nov. 9, 2000, Paris]. Promotion of such an approach has been priority for the Commission, who played an active role in the field of food safety to obtain European and international acceptance for risk analysis principles. This is illustrated by the White paper on food safety produced during 2005 by the EC and the adoption of a "modern, dynamic and effective legal framework for food safety, based on robust science", based on risk assessment. With such an approach, the use of the Precautionary Principle (as described in the Commission Communication in 2000:1 (COM 2000)) can be based on a quantitative assessment of the risk of pathogens in drinking water to human health in EU Member States. This risk can be compared to other risks and the policy of the EC to safe drinking water can be proportionate to the level of risk, consistent with other areas of consumer safety, non-discriminatory, based on cost-benefit assessments, transparent and indicates where more scientific evidence is necessary to reduce the uncertainty in the assessment of risk.

Activities are ongoing to harmonise the different aspects of risk assessment procedures (as outlined in the Commission report *The Future of Risk Assessment in the European Union*). The EU research project MicroRisk provides guidance and scientific basis for the introduction of the risk analysis principles in the area of microbial drinking water safety. This project has provided the content of this book.

In the EU-seminar about the Drinking Water Directive (DWD) in October 2003, the risk-based approach was presented as a position paper and discussed by many different stakeholders in the drinking water industry. The main conclusions concerning the value and acceptability of the risk-assessment & -management (RA/RM) approach are cited here:
"Incorporation of risk assessment and management strategies are of large added value for the DWD and for safeguarding the supply of safe drinking water that keeps the trust of consumers in the European Member States. The core principles given by WHO's Framework of Safe Drinking Water are in good agreement with the principles used by the EU in other areas of consumer safety, and are thus seen as a sound basis to be included in the revision of the DWD. For many water suppliers RA/RM is already common practice, but a more consistent approach formalises existing practices and makes them more rigorous and transparent."
From all stakeholders present at this seminar "there is broad support for the overall concept and the core principles of the RA/RM approach to be included in the revision of the DWD. Prioritisation of such an approach would be very helpful for accession countries. In a revision of the DWD the Water Safety Plans could be accommodated, where the EU should provide an overall framework of core principles and a knowledge base of health-based targets and Member States (in line

with the Subsidiarity Principle) should implement programmes and plans that are consistent with the overall framework".

4 QUANTITATIVE MICROBIAL RISK ASSESSMENT

In the Water Safety Plan, a principal question in the *System assessment* is: "Does the drinking water supply system meet the health targets?". The answer to this question can be given by a quantitative microbial risk assessment (QMRA). QMRA of fecal pathogens typically quantifies the potential risks arising from pathogens in source water, the impact of the source protection and treatment system in reducing pathogen concentrations and the risks of recontamination during distribution. QMRA gives a detailed breakdown of the contribution of each step in the chain from catchment-to-tap to the overall risk (reduction), along with the potential effects of hazardous events (such as those following heavy rainfall) and some indication of data variability and uncertainty.. The water supplier can use this information to decide where optimisation or additional control would be most effective. Hence, QMRA is also a tool to guide the risk manager to efficient control.
QMRA can be used on existing water supply systems to determine if these meet the health targets, but also on hypothetical systems to evaluate if design scenarios are potentially able to meet the health targets.

In the next paragraphs, a short description of the process of quantitative microbial risk assessment is given. For a more comprehensive description the reader is referred to Haas *et al.* [1999], Teunis *et al.* [1997], Haas & Eisenberg [2001], the ILSI framework [Benford, 2001; Teunis & Havelaar, 1999] and Medema *et al.* [2003]. Chapter 7[1] gives a description of the statistical methods used for QMRA in this document.

4.1 The process of QMRA

QMRA is derived from the chemical risk assessment paradigm, that encompasses four basic elements:
- a characterisation of the problem setting (system description), including indentification of hazards and hazardous events
- exposure assessment
- effect assessment (dose-response)
- risk characterisation

Several QMRA frameworks have been published, such as the generic ILSI framework [Benford, 2001]. In this document, most attention is given to exposure assessment and risk characterisation. We have therefore expanded the generic ILSI QMRA framework to highlight the elements that are important for exposure assessment and risk characterisation, and we have put the expanded risk assessment in the overall WHO Safe Water Framework (Figure 2).

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[1] "Chapter"referes to the corresponding chapter if the final report of MicroRisk
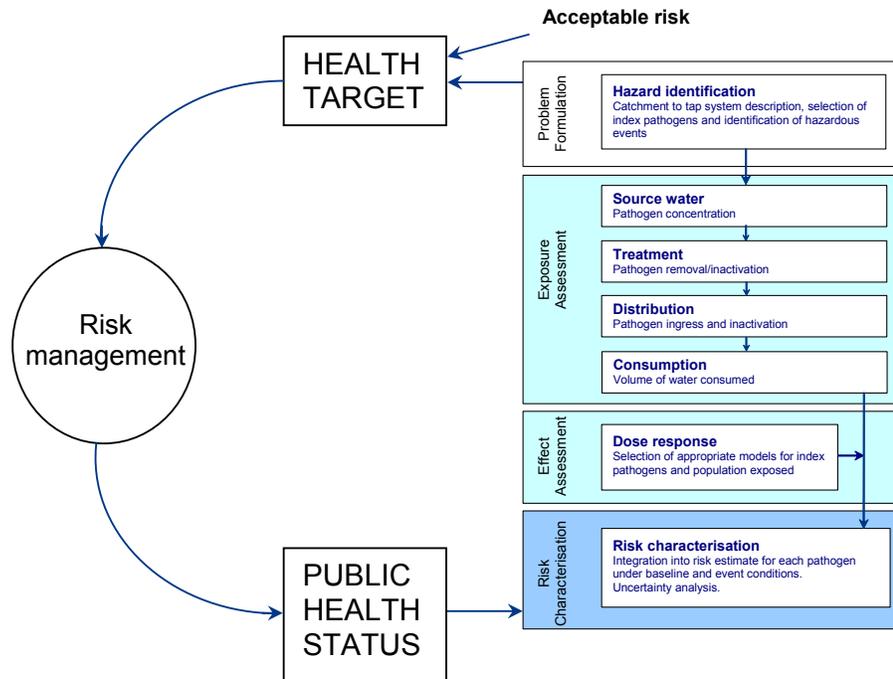
Figure 2. The steps of quantitative microbial risk assessment in the Safe Water Framework

4.2 Element 1. Problem formulation and hazard identification

This is the initialising phase of QMRA to establish which specific questions need to be addressed. The scope and the boundaries of the QMRA process are determined in this phase. This requires communication between the risk managers (regulators, public health agencies, water utilities) and the risk assessors. The basic questions to QMRA is: "Is my system able to meet the health targets?".

To conduct a QMRA, a good description of the system under evaluation is necessary and the hazards and hazardous events need to be identified. In this document, we use the definitions of the Water Safety Plan; a *hazard* is a biological agent with the potential to cause an adverse health effect and a *hazardous event* is an event or situation that may lead to the presence of a hazard in drinking water, such as a peak contamination of pathogens in source water, a treatment failure or a cross-connection with a sewer line in the distribution network. For a definition of terms used in this document, see the separate glossary.

Step 1. Description of the system from source to tap
The system for water treatment from catchment-to-tap is described, identifying the principal control elements and strategies.

Step 2. Hazard identification

Hazard identification is the identification of the micro-organisms within the system boundaries that could cause human illness, the processes by which each micro-organism finally reaches the customenr via drinking water and the type of illness(es) possible [Haas et al., 1999]. QMRA of drinking water systems is usually focussed on the ingestion of enteric pathogens and the potential for gastrointestinal illness.
The ideal QMRA does not focus on a single pathogen only, but on a suite of "index pathogens" that cover the range of health risks and control challenges for the particular water supply system defined. Adequate control of these index pathogens implies that the health risk of other known pathogens is also adequately controlled by the system and that the system also offers protection against unknown pathogens.

- Describe the characteristics of the pathogens, especially those related to waterborne transmission (survival in water, resistance to treatment etc.).
- Describe what is known about waterborne transmission, the causes of waterborne outbreaks and the relative significance of waterborne transmission compared to other routes.
- Describe the illness (type, duration, incubation time etc.) caused by the pathogens in the risk assessment, and when available information about sequellae. Describe what is known about protective immunity and secondary transmission.

Step 3. Description of hazardous events
In many cases, the majority of the risk is not determined during the normal (baseline) situation, but during hazardous events, such as rainfall leading to a high load of pathogens in source waters, or treatment failure or distribution network failure (or combinations thereof). It is therefore important to ensure that these hazardous events are incorporated in the QMRA, or that a separate QMRA is conducted to determine the (health) significance of the event.

4.3 Element 2. Exposure assessment

Exposure assessment is the quantitative assessment of the probability that drinking water consumers ingest pathogens through this drinking water. In QMRA of drinking water, this usually requires the assessment of the levels of pathogens in source water and the changes to these levels by treatment, storage and distribution, and finally the volume of water consumed.

Step 4. Assess pathogen occurrence in source water
Information about the occurrence of pathogens in source water is preferably based on a catchment survey, identifying the principal sources of contamination of the catchment and the conditions that may lead to peak events in source water, such as heavy rainfall or resuspension of sediments. Pathogen monitoring in source water can be carried out, using the information of the catchment survey, which needs to include assessment of peak events. The pathogen detection methods are ideally targeted to viable and infectious pathogens. The performance characteristics of the available detection methods for pathogens and other quality control aspects can have implications for the applicability of the data in risk assessment. These should be identified and evaluated in (the early stages of) the risk assessment process.

Step 5. Assess the elimination of pathogens during treatment
Information about the removal or inactivation of pathogens during drinking water treatment processes ideally involves data on removal of pathogens at full scale. In practice however, several other sources of data have to be used to estimate pathogen removal, such as pathogen data of pilot- or laboratory-scale systems or data on model parameters (indicator bacteria, phages, spores, particles etc.) on full-, pilot- or laboratory-scale.
The efficacy of treatment processes may vary, depending on feed water composition, operational control, temperature etc. Moments or periods of poor or suboptimal performance are hazardous events and hence most significant for risk assessment.

Step 6. Assess the changes in water quality during storage and distribution
The likelihood of recontamination of stored and distributed water (e.g. by the *E. coli* monitoring of water in these reservoirs and pipes or loss of disinfectant residual) and the significance of these contamination events needs to be assessed. In the European setting, recontamination events are rare and could be regarded as a result of a hazardous event (heavy rainfall, cross-connection, poor hygiene during repairs etc.).

Step 7. Consumption of drinking water
The last component of exposure assessment is the volume of water consumed by the population. Not only the average volume of water consumed is important, but also the person-to-person variation in consumption behaviour and especially consumption behaviour of risk groups (in terms of sensitivity to infection or high level of consumption) is relevant. The available data suggest that there is considerable difference between drinking water consumption within the population. This variation needs to be captured and incorporated in the risk assessment.
Household treatment/point-of-use devices affect the exposure. Hence, consumption data should be on consumption of drinking water without further treatment, such as heating, filters etc.
Within Europe, consumption of tap water may vary from country to country. The significance of these differences for risk assessment need to be assessed.

Step 8. Dose (exposure) estimation
Dose (or exposure) is the number of pathogens consumed per unit time. The information obtained in all the previous steps of the exposure assessment are used to estimate this ingested dose. Preferably, he dose is described stochasticly, including the variability and uncertainty in all steps of the exposure assessment.

4.4 Element 3. Effect assessment

The effect assessment is the determination of the health outcomes associated with any (level of) exposure to waterborne pathogens.

Step 9. Dose-response data
Dose-response characterises the relationship between dose magnitude, pathogen infectivity, and quantitative health effects to an exposed population. The microbial dose-response analysis records the incidence of a particular effect against dose of the agent. In most cases, this particular effect is infection, rather than symptoms of

illness. For *Cryptosporidium parvum* for instance, there is a clear relationship between ingested dose and the probability of infection, but not between dose and symptoms of intestinal illness.

Although the data-set is increasing, the number of dose-response studies with human volunteers is limited. Of most pathogens, only one or a few strains have been tested in healthy adult volunteers. Information about strain-to-strain variability and the influence of the immune response of the hosts is still limited.

There are several dose-response models available and the type of model can have a very significant impact on the response that is attributed to exposure at low doses. The models and their limitations should be well understood when applying these in QMRA. Synergistic effects between pathogens is not incorporated in the current models.

Step 10. Host Characterisation

For infectious diseases, the host susceptibility plays an important role in the health outcome of exposure. Exposure of persons with protective immunity will result in lower health outcomes than exposure of risk groups. During "Host Characterisation" the characteristics of the potentially exposed populations that are suspected for susceptibility to a particular pathogen are evaluated.

Step 11. Health outcome

Up to now, quantitative microbial risk assessment is primarily focussed on estimating the risk of infection. The relation between ingested dose and infection is relatively well-defined, while the relation between dose and other health outcomes (illness, sequellae) is not available or less clear. This is one of the reasons why it is difficult and not recommended to establish a direct relationship between QMRA (on probability of infection) and epidemiological data (on symptoms of disease). The use of the risk (or probability) of infection is justified by the degree of conservatism in using infection as an endpoint and the inability to quantify the risk of more susceptible sub-populations [Macler & Regli, 1993]. Further, infected individuals as well as those ill can pass on pathogens to others (secondary spread).

However, waterborne diseases do differ in nature, severity and duration. A metric that takes the overall health burden of waterborne diseases is necessary. Ideally, this metric can also be used to describe the burden of the disease of chemical compounds, such as carcinogens, so all different health risks can be compared on the same scale.

In the new WHO GDWQ, the concept of Disability Adjusted Life Years (DALY) [Havelaar & Melse, 2003] is introduced as the burden of disease metric in the drinking water guidelines.

The basic principle of the DALY approach is to weigh each health effect for its severity with (usually) death as the most severe outcome, multiply this weight (a factor between 0 and 1) with the duration of the health effect ('duration' of death being the remaining group life expectancy), and with the number of people in a population affected by the particular outcome. Summarizing all the health outcomes caused by a certain agent, will result in an estimate of the burden of disease attributable to this agent.

To be able to use DALY's in the QMRA, ideally the relation between exposure (dose) and different health outcomes is known. In the absence of sufficient data (which is usually the case), the dose-response relation for infection (as the first step of the disease process) can be combined with data on the fraction of the exposed population falling ill from exposure (for instance from attack rates in waterborne outbreaks) and

data on the fraction of the ill population that contract more severe health outcomes (from health surveillance data).

4.5 Element 4. Risk characterisation

In the process of risk characterisation, the information obtained in the exposure assessment and the effect assessment are integrated to obtain a risk estimate. This can be done as a point estimation: a point estimate of exposure can be entered into the dose-response relation to compute a point estimate of the risk of infection. The point estimate can be the 'best' estimate, to obtain a measure of central tendency of the risk. In the case of computing various risk scenarios, the computed point estimates give a quantitative estimate of the consequences of the circumstances that produce a risk scenario.

An stochastic approach that allows the incorporation of the variability and uncertainty in the steps of the risk assessment chain is promoted by Haas [1997] and Teunis *et al.* [1997]. This encompasses the characterisation of the distribution of all data used for risk assessment and to combine these distributions into a distribution of the computed risk, for instance by Monte Carlo analysis. This approach not only provides the risk manager with important information about the (un)certainty of the risk estimate, but also with the relative contribution of the uncertainty and variability in all steps of the risk assessment. It therefore guides the risk manager to the most appropriate options for efficiently minimising the risk and the most significant research items to reduce the overall uncertainty of the risk estimate.

With high level water supply, the baseline risk is usually very low. Under such conditions, hazardous events, such as peak contamination in the source water, treatment failure and especially the combination thereof and contamination events in the distribution network, are responsible for the majority of the risk. Most waterborne outbreaks have been traced to a (combination of hazardous events (see Chapter 1) and it is likely that many events result in the presence of pathogens in tap water and hence the transmission of disease. Wherever possible, identify and evaluate these events separately in QMRA to understand the significance of these events. Analysis of events also brings forward opportunities for optimisation of the system to prevent these events from occurring or to reduce their impact on human health.

4.6 Tiered approach to QMRA

QMRA lends itself very well for a tiered approach and this is also commonly used in risk assessment practice, both in human health risk assessment and in ecological risk assessment. The tiered approach allows an effective interaction between risk assessment and risk management, starting with a crude risk assessment, usually based on limited information to determine the urgency of the perceived problem, to prioritise the risk of different water supply sites or scenarios and to determine the need of a more detailed study for a particular situation. This allows the effective allocation of resources to the sites or situations that give rise to the highest risk. There is no a priori definition of the tiers, only that the initial QMRA is usually generic and simple and the specificity and complexity increase in subsequent tiers.

The most basic QMRA is a screening-level study. Starting with whatever information is available, a crude first evaluation is made. Usually, the available information is not specific to the system that is studied, but has to be extrapolated from the available scientific literature.

The screening-level assessment may show that the risks are negligible, without much scientific doubt. In that case, the screening-level risk assessment can be used to demonstrate the safety of the system and obviating the need for further, more detailed assessment. Alternatively, the screening-level risk assessment may imply that the risk is unacceptably high, again without much scientific doubt. In that case, the screening-level risk assessment is used to justify the installation of additional control measures. Such a screening-level risk assessment is also very useful in comparing different scenarios for risk management, e.g. different water treatment options.

If the outcome of the screening-level risk assessment is that there may be a health risk that is not negligible, there is an incentive for a next iteration of the risk assessment, collecting site-specific data, for instance on the presence of pathogens in the source water or catchment. The QMRA is repeated with the new, site-specific information. The options for the outcome of this second-tier QMRA are the same as for the first iteration. In general, one of the results of any risk assessment is the identification of which information is missing and the prioritisation of research needs [Gale, 2002].

The screening-level risk assessments usually work with point estimates of risk. The tendency is to use conservative or worst-case estimates, to "be on the safe side". But worst-case estimates, by nature and especially when used in combination, may severely overestimate the risk and it is not clear to the risk manager what the uncertainty of the calculated risk is, only that the uncertainty will be towards the lower risk values (the nature of a worst case assumption). More helpful for the risk manager is to provide a range of risks (interval estimate) that denote the variability and uncertainty in the risk estimate. In the case of the screening-level risk assessment this can be achieved by using an average, worst and best case, to illustrate the range of the risk that can be deduced from the available information and the level of certainty that is embedded in the QMRA.

Interval estimates require information about the variability and uncertainty. Variability is the result of intrinsic heterogeneity in the input of the risk assessment, such as the variation in *Cryptosporidium* concentration in source water over time, or the variation in the removal of particles by a filtration process over time. Variability can be characterised if sufficient data points are collected. Uncertainty is the result of unknown errors in inputs of the risk assessment, such as errors in the measurement of pathogens or the assumption that certain indicator organisms can be used to describe the removal of pathogens by treatment. Uncertainty can be reduced or characterised by specific research activities, e.g. to determine the recovery efficiency of the pathogen enumeration method or to compare the removal of the pathogen to indicator organisms by a treatment process.

When sufficient data are available, a probabilistic (stochastic) risk assessment can be performed, where the input is described by statistical distribution functions to describe the confidence interval of the input itself and of the calculated risk.

The tiered approach is used throughout this book, in Chapter 4 on treatment and Chapters 7 & 8 on risk assessment, where the reader can find several examples.

4.7 Risk assessment using epidemiology

The Water Safety Plan guidance document [Davison *et al.*, 2005] highlights the possibility to evaluate the performance of a water supply against health targets with an epidemiological approach. Epidemiology has a set of tools to *assess* (an estimate of) the *actual* health risk of a population and has an important role in the safe water framework, especially in the assessment of the Public Health Status and the assessment of the relative significance of the different pathogens and routes of exposure. In addition, epidemiological studies of waterborne outbreaks provide information about the events in which an outbreak may occur and are therefore very important to guide QMRA and the HACCP-based system to hazardous events. The reader is referred to Blumenthal *et al.* [2001] and Hunter *et al.* [2002], for an overview of the use of epidemiology to assess waterborne health risks.

For assessment of the health risk of drinking water supply in Europe, epidemiological tools are less applicable in practice, as the level of safety required for drinking water exceeds the level of sensitivity of (affordable) epidemiological studies. In Australia and the USA, double-blinded, randomised case control studies have been undertaken to determine the contribution of mains drinking water to the overall incidence of gastro-intestinal illness [Hellard *et al.,* 2001; Colford *et al.,* 2005]. Both studies did not show a significant relation between tap water consumption and intestinal illness. Even though these were large studies, they could only demonstrate that tap water contributed less than approx. 10% to the overall incidence of gastro-intestinal illness.
QMRA is more sensitive, but generally requires assumptions (for instance on infectivity of pathogens in water). QMRA is therefore an appropriate tool to assess the *potential* health risk of water supply systems, but less appropriate to assess the *actual* health risk of drinking water consumers.
Comparison between epidemiology and QMRA can be done in conditions in which epidemiological studies are sensitive enough to determine the risk, such as waterborne outbreaks where infection is assessed, and sufficient information on the water system is available to perform a QMRA. In practice however, the comparison is hampered by differences in health outcome; QMRA generally uses risk of infection, while epidemiology generally uses illness type, but comparison of the level of risk estimated by both means does give insight in the validity of QMRA.

5 RISK MANAGEMENT

In the EU, many drinking water supplies provide adequate and safe drinking water and have introduced quality management. What is the value of the Water Safety Plan in such a context? The experience of several pioneering water suppliers and the result of the discussions on this subject at the WHO [Water Safety conference, Berlin, April 2003], EU [EU Drinking water seminar, October 2003] and at the national level indicate that formal adoption of a Water Safety Plan and associated commitment to the approach has a number of significant benefits. As stated in the current WHO Water Safety Plan: "Major benefits of developing and implementing a water safety

plan for these supplies include the systematic and detailed assessment and prioritisation of hazards and the operational monitoring of barriers or control measures. In addition, it provides for an organised and structured system to minimise the chance of failure through oversight or lapse of management. This process ensures that safe water is continually supplied and that contingency plans are in place to respond to system failures or unforeseeable hazardous events."

Here, the steps of the HACCP-based risk management approach in the Water Safety Plan are briefly described.

5.1 Element 1. System assessment

Step 1. Assemble team and other resources

As the starting point, the management incentives are needed and a multi-disciplinary team should be assembled involving managers, engineers (operations, maintenance, design, capital investment) water quality control (microbiologists and chemists) and technical staff involved in the day to day operations with good knowledge of the system and of the safety hazards in the drinking water to be anticipated (Figure 3).
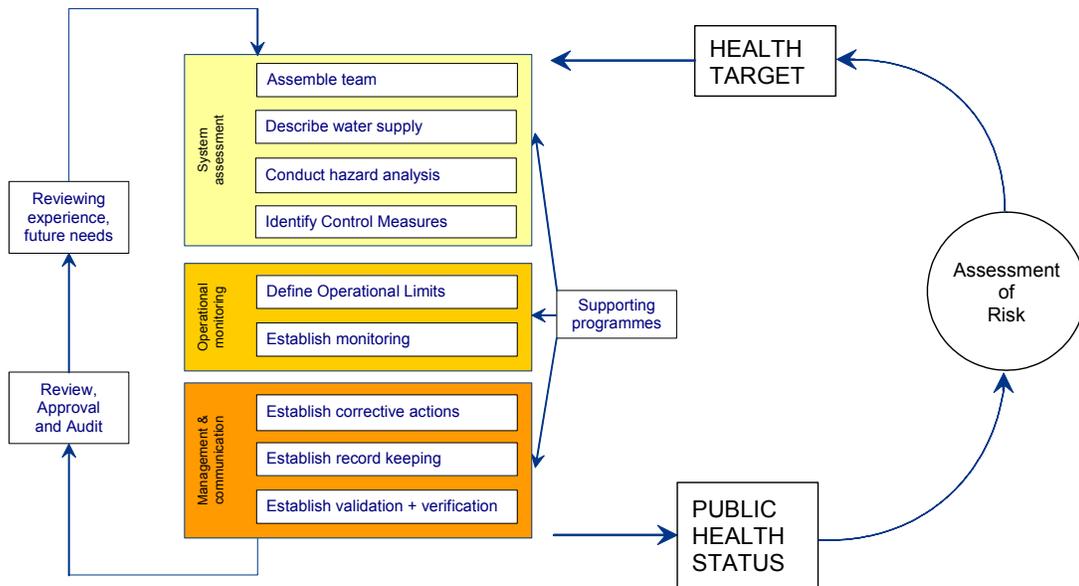
Figure 3. The steps of the Water Safety Plan in the Safe Water Framework

Step 2. Describe water supply

The team will start by preparing a description of the water supply system. This should include the catchment, source water reservoirs, water treatment processes, storage after treatment, water distribution and safe handling during household storage of water and treatment at point of use.

It is also important to describe how the water is going to be used and which routes of exposure to the water may occur. In the case of drinking water this is generally intended for human consumption and other household uses. Are there special considerations for vulnerable groups such as infants, elderly and

immunocompromised? This information is very important because it will be used to determine the potential risk of water exposure.

To enable hazards to be clearly identified it is important to develop system-specific flow charts to describe all the processes involved at each step. The WSP team should confirm that the representation of the system in the flow diagram is accurate and complete. This is important as the flow diagram is the basis for the hazard identification and tracing its potential pathways to the consumers.

Step 3. Hazard analysis

Step 3a. Identify hazardous micro-organisms
The WSP team should consider all hazardous micro-organisms (and indeed substances, but these are no part of this document) that could be associated with the water supply system under study.

Step 3b. Identify hazardous events
Identify events that may result in the presence of a hazard (in this document an enteric pathogen) in drinking water. Biological hazards (bacteria, viruses and protozoa) generally originate from contamination of water with human or animal faeces, although opportunistic bacterial and protozoan pathogens may also develop in distributed water under specific conditions. In general, faecal contamination may be used as the primary starting point for the identification of most hazardous events.

Step 3c. Prioritise hazards for control
In any system, there may be many hazards and hazardous events and potentially large number of control measures. Priorities for control measures therefore need to be defined. Prioritisation matrixes are tools to rank control measures, to provide a focus on the most significant hazards. By using a semi-quantitative risk assessment the priority score for each identified hazard/event is calculated within the need to determine the actual risk. The *likelihood* and *severity* for each risk can be calculated and a cut-off point above which all hazards are taken into consideration is established. A QMRA provides the soundest basis for prioritisation, but requires sufficient quantitative information about the probabilities of pathogen exposure during hazardous events.

Step 4. Identify control measures

"Control measures" or "barriers" are any activity that can reduce levels of hazards within water either by reducing their entry, concentration or by reducing their proliferation. The so-called "multiple-barrier-principle" is the basis for a WSP plan. The safety of drinking water cannot be warranted by a single barrier or control measure, but only by a suite of control measures in the whole supply chain from catchment to consumer. This includes control measures in the catchment, the water collection, treatment and distribution system and the domestic installation of the consumer.

Control measures in the catchment should prevent hazards entering the water supply chain. This is in line with the European Framework Directive and draft of the Groundwater Directive. Guidelines/Codes of practice on how to define drinking water protective areas are available (DVGW W 101/102 "Protective Areas for Groundwater, reservoirs").

For some engineered control measures (i.e. treatment processes) limits for operational acceptability can be defined, and operation can be monitored directly or indirectly (step 6). Examples are ozonation, of which the efficacy can be monitored with ozone residual, contact time and water temperature or ultrafiltration of which the efficacy can be monitored by particle counting. Other control measures cannot be monitored in a similar fashion but are still equally important. Examples are a catchment protection programme or the Operation Procedures for maintenance of distribution networks that include hygiene considerations. Adherence to these are important control measures, and therefore part of the Water Safety Plan. These control measures can be considered in Supporting Programs (Step 6).

5.3 Element 2. Operational monitoring

Step 5. Define operational and critical limits
For control measures, operational and critical limits are established. Limits are set for parameters that can be monitored or aspects that can be observed and give information about the adequacy of the control measure. A Critical Limit (CL) is a performance target that, if exceeded, indicates that the ability of the supply to meet the water quality targets is compromised. This requires immediate actions to correct this.
In current water supply practice, operational limits are usually set in addition to critical limits. Operational limits are set for the same parameters as the critical limits, but the operational limits are stricter and trigger remedial actions (for example increase of the disinfectant dose when the residual disinfectant concentration is too low), before the control measure is reaching or passing its critical limit. Current knowledge and expertise (industry standards, technical data and locally derived historical data) can be used as guide to determine the limits.

Step 6. Establish monitoring system
Monitoring are all the actions of conducting a planned sequence of measurements or observations of control parameters to assess whether a control measure is operating properly. Some control measures, such as many treatment processes, allow monitoring systems for process or water quality parameters that indicate the efficacy of control (such as disinfectant residual, UV-intensity, turbidity, particle counts etc.). The use of automation in control of treatment processes is increasing rapidly in water supply companies. The use of SCADA (Supervisory Control and Data Acquisition) system uses on-line measurement systems that collect data on treatment performance very frequently. These systems have critical limits put in to guide control or raise an alarm for the operator. To date, these limits are not based on a quantitative assessment of the contribution of the treatment process to the overall safety of the system, but on rules-of- thumb/experience. QMRA has the ability to base the limits on a quantitative science-based assessment (see Chapter 8).
Other control measures require a different type of monitoring. Examples are inspection of hygienic maintenance operations of the distribution network, inspection of the integrity of infrastructure (storage reservoirs etc.).
If monitoring shows that an operational or critical limit has been exceeded then there is the potential for water to become unsafe. Monitoring should be performed according to a statistically valid sampling plan (particularly including event conditions) to prevent the supply of any potentially unsafe water.

Microbiological assays, such as for indicator organisms (*E. coli* and others), are generally still too slow and infrequent to guide for process control, hence form part of system verification (Step 9b). With the developments of molecular methods and lab-on-a-chip techniques the possibility of on-line microbial monitoring comes closer, but these methods are currently too insensitive for use in drinking water practice to monitor treatment performance or distribution integrity.

5.3 Element 3. Management & communication

Step 7. Establish corrective actions
Corrective actions are the actions taken when the results of monitoring indicate a loss of control. It is necessary to detect deviations through monitoring and respond through corrective action to prevent unsafe water being supplied. The corrective action will protect water safety by bringing the control point back into specifications by enhancing the control point or by implementing additional control measures. All these actions should be completed in a sufficient time frame adequate to maintain water safety.

In some cases, significant deviations occur in control measures that are outside of the scope of corrective actions. Such unpredictable incidents occur occasionally and require an incident response. The use of backup disinfection plants or spot dosing may be used to correct disinfection system failure within the water supply. By ensuring that a contingency is available and promptly applied in the event of an operational or critical limit being exceeded, safety of supply can be maintained.

Incident and emergency (natural disaster, deliberate contamination etc.) response plans are necessary to ensure the provision of safe drinking water under these conditions.

Step 8. Establish record keeping
Types of records that can be kept are support documentation for developing the WSP, records generated by the WSP system, documentation of methods and procedures used and records of employee training programs, all part of ISO reporting procedures**.**

Step 9. Establish validation and verification

Step 9a.Validation
Validation is an investigative activity to identify the effectiveness of a control measure, typically when a system is designed or rehabilitated. It is applied to ensure that the systems used in the WSP are effective and controls the hazard. Evidence to support the WSPs can come from a wide variety of sources such as scientific literature, trade association, regulation and legislation departments, historical data, professional bodies or supplier knowledge. An example is a UV system that is needed for a three log *Cryptosporidium* inactivation. The information on *Cryptosporidium* inactivation by UV is collected from the scientific literature and the dose delivery of the UV system is validated according to national standards/guidelines. Alternatively, challenge testing is applied to the full-scale barrier being validated, such as sulphite-reducing clostridia removal across a sand filter as a surrogate for *Cryptosporidium* oocyst removal.

Step 9b. Verification
Verification is the final check of the safety of the water supply system. For microbiological safety, verification is typically the monitoring for faecal indicators in treated water and in distribution. Traditionally *Escherichia coli* is used for verification monitoring.
Since *E. coli* is more sensitive to disinfection than viruses and protozoa, additional parameters, such as *Clostridium perfringens* and bacteriophages, may be needed for adequate verification.

5.4 Support programmes

Adequate training of personnel, involvement of all stakeholders in the provision of safe water, the development of technical standards for good operation or monitoring methods are all examples of supporting programmes that are relevant for the provision of safe water, but do not affect water quality directly. Many of such programmes are already present in water supply companies in the EU. The WSP should be composed in co-ordination with these programmes.

6 THE LINKS

At various steps in the HACCP-based process, questions emerge that relate to the balance between safety and costs of the water supply system. More safety can be obtained by including additional control measures, by setting very strict limits, by intensive monitoring etc. However, resources are not unlimited and drinking water is not the only transmission route for pathogens and toxic compounds that needs to be controlled. In the European setting, drinking water safety is well established and other routes (food, recreational water) of exposure are much more important for consumer health.
QMRA provides information for efficient allocation of resources to water supply. By setting health-based targets based on the contribution of drinking water to the overall health risk of the human population, it becomes clear when *safe* is *safe enough*. Links between QMRA and WSP are illustrated by the questions it answers in Figure 4.

Risk management questions that need quantification:
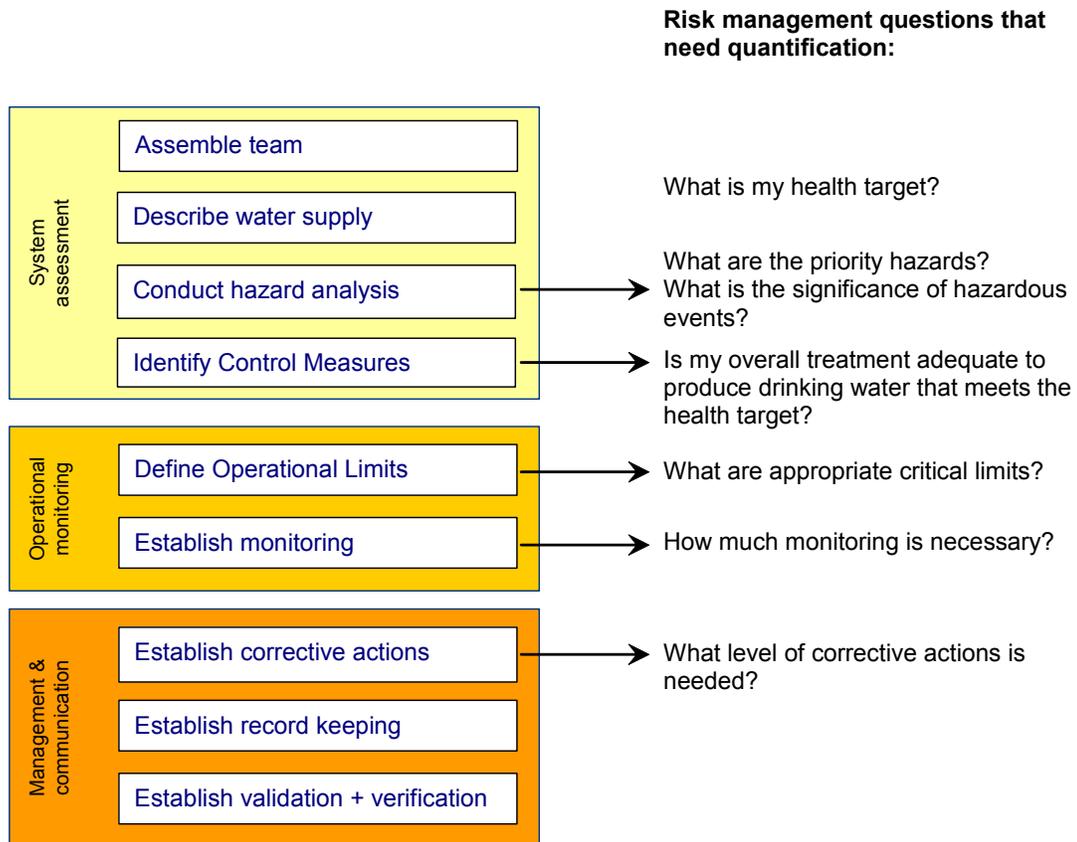
Figure 4. Risk management questions that relate to the balance between safety and costs that can be answered by QMRA

6.1 Link 1: Health targets

Setting of a health target
This link is already represented in the overall framework (Figure 1). The risk assessment is used to determine the risk related to drinking water. The risk estimate and the level of risk that is considered tolerable in relation to drinking water is translated into a health target. A health target is generally a tolerable disease burden (1μ DALY.y^{-1}) or annual infection risk (10^{-4}.y^{-1}), but can be translated into a water quality target or performance targets [see also WHO GDWQ, 2004]. Setting the health target is the responsibility of the regulator and the target they set for drinking water is the starting point for risk management by the water supplier. They need to design, operate, control and maintain their system in a way that ensures that the health target is met at all times.

Complying with the health target
At the water utility level, a QMRA can be conducted to answer the question: "Do we meet the health target?". It is the responsibility of the water utilities to meet the health-based targets and to demonstrate to the regulators and the public that these targets are met. During the HACCP-based process the risks are approached in a semi-

quantitative manner (high, medium, low etc.), based on experience, industry standards and subject to personal interpretation. In many cases, this is sufficient information for risk management; i.e. it is clear that a well-head that is not properly closed may give rise to contamination of the water from the well and the corrective action will be to close the well-head properly. In these cases, there is usually no further quantitative assessment of the risk of contamination necessary to trigger the appropriate corrective actions.

However, this does not answer the question whether the overall water supply system from source-to-tap provides safe drinking water to the consumer. A quantitative microbial risk assessment of a drinking water system can demonstrate that the health-based targets are met. In the European setting, water supply systems are usually well-developed, operated and maintained. The question is there "Are more risk management measures necessary or is the system safe enough?". QMRA can answer this question and provide justification that sufficient resources are allocated to the provision of safe drinking water to the consumers.

A QMRA (in the WSP: System assessment) is therefore the logical first step when safety of a water supply system is under consideration. The outcome of this assessment will be the basis for further development.

If the outcome indicates that overall system is adequate to provide the consumers with safe drinking water, the HACCP-based process can be used to guarantee this safety is met under all conditions.

If the outcome of the assessment indicates that the drinking water could be unsafe under some conditions, the water supply system (management) needs to be adapted. The effect of different solutions can be investigated by using the QMRA as a scenario-study tool. Feeding the alternatives into the QMRA will help to identify the most economic, sufficiently effective measure to bring the risk within the health based targets. These measures can be either physical (covering clean water reservoirs, new treatment processes), operational (new critical limits) or management measures (reducing human or domestic animal activities in catchments).

6.2. Link 2: Hazardous events are risk events

Hazard identification to guide QMRA to risk events
In the HACCP-based system, hazards and hazardous events are identified and prioritised. These hazardous events are significant information for risk assessment as they may comprise most of the health risk. Bartram *et al.* [2001] already identified that QMRA should not only be directed at the nominal performance of treatment systems, but also at the moments of poor source water quality and treatment performance. Knowledge about hazardous events and their probability of occurrence can be used in QMRA as risk scenarios (see Chapter 8).

QMRA to guide Hazard identification to risk events
Similarly, during exposure assessment information is collected about occurrence of pathogens in source waters, treatment efficiency and distribution system integrity. This may yield information about peak events in source water, moments or periods of suboptimal treatment performance and distribution integrity breaches, and thus about hazardous events. This can be used in the process of hazard identification and prioritisation.

Objective risk priorities with QMRA
In the HACCP-based system, fault trees and Risk Factor Matrices are used to provide a focus on the most significant hazards and hazardous events. The priorities are set on the basis of expert judgement and historical data. Several ways to prioritise hazards in this semi-quantitative manner are described by Davison *et al.* [2002]. The estimation of occurrence and effects is subjective to personal knowledge and experience of the WSP-team members. Therefore hazards that have already occurred are likely to be weighted more heavily than yet unknown hazards. This could lead to high unnecessary investments or overseeing relevant risks.
QMRA can be used for quantitative estimates of the different routes of contamination, improvement against a major transmission route is most important as long as it is still major. Improvement of control over major routes (for instance improving surface water treatment) enhances the importance of minor routes and these minor routes need to be taken into consideration. An example is the ingress of contamination in the distribution network in an appropriately-treated water. Improving treatment may be less effective than reducing the probability of ingress in the network.
QMRA can also be used to determine the significance of "bad days" (temporal effect, periods of poor treatment performance): treatment efficacy varies, and the majority of the risk is associated with bad days, moments of poor treatment performance.
Similarly QMRA can establish the significance of "by-passes" of critical control points (spatial effect) such as one poorly performing filter in a set of parallel filters. If the performance of this one filter is severely compromised, the proper performance of the other filters does not compensate this.
HACCP can address the bad days but is less appropriate for assessing the minor routes and the by-pass. QMRA can help in addressing the important elements in the system.

Using QMRA to prioritise hazards will result in an objective, quantitative prioritisation of the hazards, provided there is sufficient quantitative information available.
QMRA can compare the risk of different hazards and hazardous events in alternative scenarios. Examples of this are:

- a surface water utility wants to focus the limited resources on monitoring of the most critical pathogen(s). A QMRA will establish the efficacy of the treatment system against the different pathogens and allow the selection of the pathogens that pose the largest control challenge, or
- the impact of a peak rainfall event in the catchment or of the failure of disinfection process can be determined quantitatively and hence objectively prioritised.

6.3 Link 3: Health target can be translated into target and critical limits

In the HACCP-based system, there is no direct link between the target or critical limits on system operation and the health target. The overall system needs to produce and deliver water that is safe. Safety is defined as meeting the health (or related water

quality) target. Operational limits should be set at levels that ensures the treatment produces water that meets the health target. Target limits are criteria that indicate whether a control measure is functioning as designed. If monitoring shows that the target limit is exceeded, predetermined corrective actions should be put into operation to 1) ensure the system continues to meet the health target and 2) bring the control measure back into its limits. Exceedance of *critical limits* is more serious for microbiological water quality, since this means the system is not complying with the health target. This is often referred to as incident.

Setting of target and critical limits for operations may also have significant consequences for the cost of water supply; stricter limits will generally imply higher costs for catchment protection, treatment or distribution (maintenance). A sound basis for setting the limits at a level that optimises safety and costs is therefore appropriate. *Control charts* are often utilised to track changes in performance against the *Target Limits*, as they provide a good visual clue to operators and assist in identifying a trend towards a potential problem before it occurs.

To reach appropriate target and critical limits for control measures, QMRA can be applied to ensure that the resulting water quality will always comply with the health targets.

Exposure assessment for QMRA provides information about the contribution of individual steps of the multiple barrier system to the overall exposure. In other words, the exposure assessment provides information about the relative contribution of the control measures to the overall risk estimate. With the health (risk) target as reference, the required contribution of individual control measures to produce and deliver drinking water that meets the health target can be assessed. This can be translated into critical limits for individual control measures.

Setting of appropriate target and critical limits is complex and may have significant impact on safety and costs. Arriving at the optimal limits will need several iterations, using practical experience and ongoing scientific insights to further improve the operation of the water system. Critical limits will depend on circumstances such as water temperature or source water turbidity. For complicated systems a real-time computer model of the water supply system (for disinfection and other water quality parameters) may be helpful in maintaining optimal water quality and choosing the most appropriate corrective measures.

6.4 Link 4: Designing monitoring programs

Monitoring will determine the period for which a possible failure of the water supply system may remain unnoticed. It is obvious that a longer exposure time will result in an increased risk. However monitoring and verification will require resources and funds, and cannot be applied limitlessly. QMRA can provide validation of the monitoring plan, by determining the risk when the maximum period of (unnoticed) exposure is reached. Thus funds and resources can be divided in such a way that maximum safety for the consumers is warranted.

The monitoring results can provide information about source water quality, treatment efficacy and the integrity of the distribution system. This information is important input for the next iterations of the QMRA, as it provides information about the extend of variation in source water quality, efficacy of treatment processes

and distribution system integrity. This is important to assess the level of certainty of risk estimates, but also to guide QMRA (and indeed HACCP) to hazardous events (how often does a peak contamination occur in source water and to what extend?; how variable is the efficacy of the disinfection process and under which conditions is the efficacy compromised?). In general, the first iterations will be based on expert knowledge and available data from literature and historical data on site, but as the WSP becomes implemented, more and more site-specific data will come available to improve both the HACCP-based and QMRA-process.

6.5. Link 5: Selecting corrective actions

Corrective actions
When target limits are exceeded, corrective actions are needed to keep the system under control. If critical limits are exceeded, urgent actions are required in order to prevent non-compliance with the health target and hence an increased health risk. Different levels of corrective actions may be undertaken. These could be restricted to the control measure that is out of bounds, but could also include other control measures that may be enhanced or even already working at a relatively high efficiency. QMRA can be used to determine to what extend exceeding the limits of the individual control measure is actually resulting in non-compliance of the system as a whole. If that is the case, QMRA can also be used to select the most appropriate corrective actions under the given conditions, as it looks at the system as a whole, rather than at individual control measures.
An example of such a situation is a groundwater system that is under the influence of surface water. Under nominal conditions, the passage of the surface water through the soil is slow and pathogens are effectively removed, indicated by the absence of indicators in the groundwater. During rainfall events, the situation is different, pathogen transport is rapid and the groundwater may become contaminated, as indicated by the presence of surrogates. UV could be installed to prevent the water of becoming unsafe under these adverse conditions. It is not possible to correct the efficacy of the soil passage during these events, but it is possible to enhance the UV as a reaction to this situation. The level of enhancement of UV can be tailored by the level of contamination found in the groundwater under such conditions.

Treatment design: comparing alternatives
During the design of a water treatment plant, or when changes to a treatment plant are required, one needs to choose between different solutions. Each (combination of) solutions needs to comply with the health based targets. A QMRA can help identifying the most economical alternative. Thus unnecessary investments can be avoided. Here, QMRA can be used as a design tool.

7 OUTLOOK

7.1 New iterative approach for safe drinking water

The Water Safety Plan is a 're-invention' of common sense that can be used by water utilities for efficient, comprehensive, transparent and documented risk management. The WSP has already been successfully piloted by water utilities in several countries outside the EU and is now being piloted within the EU. The WSP (re-)focuses the attention of the water utilities on controlling and maintaining the whole system from source-to-tap, rather than the focus on end-product monitoring. The WSP will also change the way various drinking water inspectorates and government will operate to ensure that health targets are met. Rather than looking at the monitoring data from the treated water, the inspectors/auditors can focus more and more on the success of the WSP.
Implementation of WSP will produce and document a wealth of data about the occurrence of hazards and hazardous events and the efficacy of the control measures to cope with these. The implementation should therefore be regarded as an iterative process in which more information becomes available in every cycle to improve the risk management process. Similarly, QMRA can be fed with more and more site-specific data to improve the reliability of the risk assessment.

7.2 The value of QMRA

Water suppliers that use the HACCP-based process are faced at several steps in this process with questions of a quantitative nature. The first question is:
• Is my system meeting the health-based targets?
This typically needs a quantitative risk assessment (System assessment (WSP)).
Other questions that require quantitative answers are:
• What is the priority of different hazards/hazardous events; so where do I focus my risk management on?
• Where do I set my operational and critical limits?
• How much monitoring is necessary?
• What level of corrective actions is necessary?
The answers to these questions are usually based on semi-quantitative expert judgements and industry or legal standards. QMRA provides more objective, science-based and quantitative information to answer these questions and hence a more precise basis for risk management. This is particularly relevant in cases where the costs of (additional) control measures or corrective actions are high. In such cases, the high costs are an incentive to collect the quantitative information that is needed to perform a QMRA.

7.3 State of the art

Risk assessment allows comparison of the effort and resources put into the provision of safe drinking water against resources allocated to manage other health risks. However, given the current state-of -the-art and especially the lack of available quantitative data, QMRA of a water supply system has to rely partly on

assumptions. Given the current level of uncertainty in quantitative risk assessments of drinking water supplies, the outcome should be regarded as an indication of the level of safety, rather than an absolute assessment of health risk. The outcome can be used to guide the risk management direction to pathogen control and to select the most appropriate control measures.

The benefit of risk assessment is that it gives a better understanding/breakdown of the problems and identifies what is important data. Additionally, the risk concept allows us to focus and prioritise research to the areas where important pieces of information are missing.

The large variability of pathogens in source waters and the limited availability of data (esp. in relation to peak events) and the variability in treatment efficacy are very important issues to take into consideration in QMRA. More data need to be collected and monitoring programs of water suppliers should be targeted more towards the provision of information for QMRA. The variability and limited data available will cause uncertainty in the risk assessment, but compared to chemical risk assessment with large uncertainty factors, this is not inhibitive for the implementation of microbial risk assessment, as illustrated in Chapter 8.

Pathogens to be selected for QMRA (and hence the MicroRisk project) should be detectable in source waters with reliable analytical techniques. The use of selected 'index pathogens', pathogens that are critical to determine if the control measures taken in water supply result in drinking water that meets the health target, are recommended. Control of these index pathogens would mean control of the other known (and even unknown) pathogens that behave in a similar way.

Most of the risk assessment in water supply is currently undertaken on large surface water supplies. The risk assessment framework should be applicable in many different situations in Europe; also in areas with high numbers of small supplies, in areas dominated by ground water sources, in tourist areas and recreational settings. Experience with the use of QMRA in these other areas is needed to evaluate the applicability under these diverse conditions.

7.4 Stakeholder participation

The water supplier
Water suppliers in Europe have implemented or are implementing several management systems that relate to Water Safety Plans; systems for quality management, systems for ensuring safety against deliberate contaminations, systems for ensuring continuous supply of drinking water, asset management systems, maintenance plans etc. In many of these systems, specifications are given for design of systems, operational procedures, maintenance, repair etc. When a Water Safety Plan is prepared, the links with the other systems should be established. The value of the Water Safety Plan is that the focus is on hazards/hazardous events, how these are controlled and how this control is warranted by monitoring programs and plans for response to system failures. Other management systems and current practice tend to focus on describing how things *should be* done, the Water Safety Plan focuses on monitoring that things *are* done and how they should be done.

The regulator
For implementation, the risk-based approach needs to be endorsed by the regulator of drinking water policy. The regulator needs to define the level of risk that is considered tolerable through drinking water. This is not new, water quality standards for several chemical compounds in the WHO Guidelines for Drinking Water Quality have been derived from a tolerable lifetime risk of 1 case of cancer in 100,000 people. Also the EU uses this approach in the Drinking Water Directive, only their tolerable risk level is 10 times stricter (1 cancer-case per 1 million people). However, for pathogenic micro-organisms, no such tolerable risk level is defined in the EU.
Ideally, a reference level of tolerable risk through drinking water is defined, incorporating the burden of disease, for all health risks, be it microbiological, chemical or otherwise. As stated earlier, the WHO is using the DALY's as a metric and has derived a new reference level of risk of 10^{-6} DALY's per person per year from its current tolerable risk level for carcinogens (<1 cancer-case per 100,000 people (lifetime risk)) (see WHO GDWQ, and the discussion in Chapter 7).
The need for a reference level of risk was highlighted at the EU drinking water seminar in 2003. Before the risk-approach can be implemented in the Drinking Water Directive, the EU needs to define this reference level of risk. The definition should be considered with great care and stakeholder consultation, especially the health authority, as the level of risk that is considered tolerable through drinking water has important implications for adequate health protection, consumer confidence and cost of water supply.

The regulator has a second role in the protection of the safety of drinking water. The water supplier is responsible for adequate control of the hazards and hazardous events that occur in the systems that they are controlling (abstraction, treatment, distribution). However, hazards originate from sources over which many water suppliers have no control. The discharge of treated or untreated sewage in the catchment, combined sewer overflows or agricultural practices that occur in the catchment result in the presence of pathogens at the sites where water suppliers abstract their surface water for the production of drinking water. Reduction of the pathogen load to surface water by additional sewage treatment, removal/relocation of overflows and the implementation of protection zones around stretches of surface water that are vulnerable to surface run-off are all control measures that should be part of the multiple barrier approach in providing safe drinking water. Similarly, protection of groundwater is of primary importance. The increasing urbanisation makes it increasingly necessary to combine the water supply function of land with other functions. This combination should not compromise the safety of the water supply system.
As many outbreaks of waterborne disease have occurred due to an event in the catchment that lead to high pathogen levels at the abstraction sites (heavy rainfall, snowmelt, contamination accidents etc.), implementation of measures to control pathogen discharge into the catchment are important to reduce the risk of disease through drinking water. The Water Framework Directive does specify this in a very general manner, but more specific guidance and regulations are needed.

The consumer: risk communication
The majority of Europeans have confidence in the safety of their drinking water. The consumer expects a high level of safety from drinking water, as they do not have free

choice of their drinking water. The consumer should be informed about the risk-based approach and the level of risk that is considered tolerable. Risk communication is delicate; transparent and open communication is important, as well as the choice of wording (i.e. talk about risk assessment or about safety assessment). The Water *Safety* Plan is an instrument that water suppliers can use for communicating due diligence to their consumers. It demonstrates that the water supplier has made a systematic inventory of all possible hazards/hazardous events, has control measures in place to deal with these hazards effectively and monitors whether the control measures are working all the time. Water Safety Plans will not totally eradicate waterborne outbreaks, but they will improve the standard of water supply even further.

The inspector: auditing

In the current EU Drinking Water Directive and in national legislation, water quality is primarily regulated through standards for chemical substances, physical condition and micro-organisms. The role of the inspectorate is therefore in principal to check if the water supplied meets the drinking water standards and to ask for improvements in water supply if standards are not met. In the risk-based system, the role of water quality standards and monitoring of finished water or water at the tap changes to the verification that all systems are designed and operated appropriately. In the Water Safety Plan, the water supplier documents the hazards and their control. The role of the inspectorate will shift towards an auditing process (or maybe even to auditing of the auditing done by an independent auditing agency, as is seen with the implementation of HACCP in the food industry). Science is needed to support this audit process, for instance to determine how much *E. coli* monitoring is needed to verify that the supply system is providing microbiologically safe drinking water.

The health authority: is risk management effective and efficient in terms of public health?

The WSP is a tool for the risk management process at water utilities. This is focused on the prevention of transmission of waterborne illness through drinking water. The point of reference are the health (or related water quality) targets, but the risk management process in itself has no means to verify if the risk management actions sufficiently improve the public health status (or indeed lead to an imbalance in the allocation of resources to prevent waterborne illness, while other routes of exposure are much more significant). It is therefore important to "calibrate" the WSP with public health surveillance, taking into consideration disease outbreaks as well as sporadic cases of illness in the population who may be exposed to pathogenic microorganisms from a range of sources, not just drinking water. Health authorities may also undertake research to evaluate the role of water as a risk factor in disease, for example through case-control, cohort studies or intervention studies. In the case of an outbreak of illness that could be waterborne (see Chapter 1), the health authority will approach the water supplier to check whether water supply could be the source, for instance because the supply system is compromised. With a Water Safety Plan implemented, the water supplier can clearly demonstrate whether this was the case or not.

7.5 Future outlook: monitoring drinking water safety on-line

The future possibility of this approach is to design an on-line system for establishing and maintaining drinking water safety. The current monitoring for *E. coli* in treated water is valuable as a verification tool that the system has produced drinking water of good quality. The aim of this approach is to be able to determine this on-line and provide the treatment plant operator with information and tools to maintain the safety of drinking water instantaneously.

The efficacy of the total treatment that is required to produce safe drinking water from the given source water quality can be regarded as the Critical Limit of the overall treatment; if this limit is exceeded, the required treatment efficacy is not met and this may result in a health risk from drinking water that is above the target. The monitoring program of the Control Points in the WSP monitors the performance of the individual treatment processes. This could be combined into an on-line assessment of the overall treatment efficacy, with the contribution of the individual processes. This way, the plant operator can see the efficacy of the treatment system on-line and can compare this against the Target and Critical Limit, the required treatment efficacy. If limits are not met, corrective actions need to be taken. This system allows not only to monitor the enhancement of the treatment performance on-line, but also to use different types of control measures to return to safe drinking water as rapidly and efficiently as possible.

Such an on-line control system can range from a simple assessment of key parameters at the relevant Control Points to an advanced model for treatment efficacy that uses the data from the WSP monitoring as input. A simple version (that is in operation at present) is the use of the AWWA/EPA Guidance manual for obtaining log-credits for treatment processes. At a treatment plant with coagulation/filtration and ozone, on-line information about temperature, pH, coagulant dose, turbidity, ozone residual and water flow was collected. For the ozonation, this was transformed (using the tables on the ozone efficacy in the guidance manual) to a log-removal of viruses, *Giardia* and *Cryptosporidium*. The efficacy of the coagulation/filtration was set at 2 logs for as long as the coagulation operated within the operational limits. The operator received this information as a line on his monitor of the efficacy of the total treatment system and the contribution of the two processes. The critical limit of the overall efficacy was the treatment efficacy required under the Surface Water Treatment Rule.

More and more advanced tools for on-line monitoring, data handling and process control become available. As stated above, the implementation of the WSP with QMRA will produce a wealth of data that can be used to improve on-line process control. As more and more data and tools become available, the implementation of on-line process control systems that are directly linked to the safety of the drinking water is within reach. A point of caution, however, is that such instrumentation requires careful calibration and checking, as it is easy to accept numbers without questioning them from a machine.

It should be clear that on-line monitoring can typically be applied to monitor source water quality and the performance of treatment processes. It is less easily applied on control measures such as hygienic procedures for mains repair or inspection of well-heads or service reservoirs for leakage. This latter inspection-type monitoring is equally important for ensuring the safety of drinking water. In this form of monitoring, constant vigilance is needed to prevent contamination events. Reduced

monitoring frequency causes slow deterioration of the water supply system and operational procedures and may ultimately lead to contamination of drinking water with waterborne pathogens and disease cases.

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