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Health-based targets

3.1 Role and purpose of health-based targets

Health-based targets should be part of overall public health policy, taking into account status and trends and the contribution of drinking-water to the transmission of infectious disease and to overall exposure to hazardous chemicals both in individual settings and within overall health management. The purpose of setting targets is to mark out milestones to guide and chart progress towards a predetermined health and/or water safety goal. To ensure effective health protection and improvement, targets need to be realistic and relevant to local conditions (including economic, environmental, social and cultural conditions) and financial, technical and institutional resources. This normally implies periodic review and updating of priorities and targets and, in turn, that norms and standards should be periodically updated to take account of these factors and the changes in available information (see section 2.3).

Health-based targets provide a “benchmark” for water suppliers. They provide information with which to evaluate the adequacy of existing installations and policies and assist in identifying the level and type of inspection and analytical verification that are appropriate and in developing auditing schemes. Health-based targets underpin the development of WSPs and verification of their successful implementation. They should lead to improvements in public health outcomes.

Health-based targets should assist in determining specific interventions appropriate to delivering safe drinking-water, including control measures such as source protection and treatment processes.

The use of health-based targets is applicable in countries at all levels of development. Different types of target will be applicable for different purposes, so that in most countries several types of target may be used for various purposes. Care must be taken to develop targets that account for the exposures that contribute most to

The judgement of safety – or what is a tolerable risk in particular circumstances – is a matter in which society as a whole has a role to play. The final judgement as to whether the benefit resulting from the adoption of any of the health-based targets justifies the cost is for each country to decide.

disease. Care must also be taken to reflect the advantages of progressive, incremental improvement, which will often be based on categorization of public health risk (see section 4.1.2).

Health-based targets are typically national in character. Using information and approaches in these Guidelines, national authorities should be able to establish health-based targets that will protect and improve drinking-water quality and, consequently, human health and also support the best use of available resources in specific national and local circumstances.

In order to minimize the likelihood of outbreaks of disease, care is required to account properly for drinking-water supply performance both in steady state and during maintenance and periods of short-term water quality deterioration. Performance of the drinking-water system during short-term events (such as variation in source water quality, system challenges and process problems) must therefore be considered in the development of health-based targets. Both short-term and catastrophic events can result in periods of very degraded source water quality and greatly decreased efficiency in many processes, both of which provide a logical and sound justification for the long-established “multiple-barrier principle” in water safety.

The processes of formulating, implementing and evaluating health-based targets provide benefits to the overall preventive management of drinking-water quality. These benefits are outlined in Table 3.1.

Targets can be a helpful tool both for encouraging and for measuring incremental progress in improving drinking-water quality management. Improvements can relate to the scientific basis for target setting, progressive evolution to target types that more precisely reflect the health protection goals and the use of targets in defining and promoting categorization for progressive improvement, especially of existing water supplies. Water quality managers, be they suppliers or legislators, should aim at continuously improving water quality management. An example of phased improvement

Table 3.1 Benefits of health-based targets

Target development stage	Benefit
Formulation	Provides insight into the health of the population Reveals gaps in knowledge Supports priority setting Increases the transparency of health policy Promotes consistency among national health programmes Stimulates debate
Implementation	Inspires and motivates collaborating authorities to take action Improves commitment Fosters accountability Guides the rational allocation of resources
Evaluation	Supplies established milestones for incremental improvements Provides opportunity to take action to correct deficiencies and/or deviations Identifies data needs and discrepancies

is given in section 5.4. The degree of improvement may be large, as in moving from the initial phase to the intermediate phase, or relatively small.

Ideally, health-based targets should be set using quantitative risk assessment and should take into account local conditions and hazards. In practice, however, they may evolve from epidemiological evidence of waterborne disease based on surveillance, intervention studies or historical precedent or be adapted from international practice and guidance.

3.2 Types of health-based targets

The approaches presented here for developing health-based targets are based on a consistent framework applicable to all types of hazards and for all types of water supplies (see Table 3.2 and below). This offers flexibility to account for national priorities and to support a risk–benefit approach. The framework includes different types of health-based targets. They differ considerably with respect to the amount of resources needed to develop and implement the targets and in relation to the precision with which the public health benefits of risk management actions can be defined. Target types at the bottom of Table 3.2 require least interpretation by practitioners in implementation but depend on a number of assumptions. The targets towards the top of the table require considerably greater scientific and technical underpinning in order to overcome the need to make assumptions and are therefore more precisely related to the level of health protection. The framework is forward looking, in that currently critical data for developing the next stage of target setting may not be available, and a need to collect additional data may become obvious.

Establishing health-based targets should take account not only of “steady-state” conditions but also the possibility of short-term events (such as variation in environmental water quality, system challenges and process problems) that may lead to significant risk to public health.

For microbial pathogens, health-based targets will employ groups of selected pathogens that combine both control challenges and health significance in terms of health hazard and other relevant data. More than one pathogen is required in order to assess the diverse range of challenges to the safeguards available. Where the burden of waterborne microbial disease is high, health-based targets can be based on achieving a measurable reduction in the existing levels of community disease, such as diarrhoea or cholera, as an incremental step in public health improvement of drinking-water quality. While health-based targets may be expressed in terms of tolerable exposure to specific pathogens (i.e., WQTs), care is required in relating this to overall population exposure, which may be focused on short periods of time, and such targets are inappropriate for direct pathogen monitoring. These conditions relate to the recognized phenomenon of short periods of decreased efficiency in many processes and provide a logical justification for the long-established multiple-barrier principle in water safety. Targets must also account for background rates of disease during normal conditions of drinking-water supply performance and efficiency.

Table 3.2 Nature, application and assessment of health-based targets

Type of target	Nature of target	Typical applications	Assessment
Health outcome			
• epidemiology based	Reduction in detected disease incidence or prevalence	Microbial or chemical hazards with high measurable disease burden largely water-associated	Public health surveillance and analytical epidemiology
• risk assessment based	Tolerable level of risk from contaminants in drinking-water, absolute or as a fraction of the total burden by all exposures	Microbial or chemical hazards in situations where disease burden is low or cannot be measured directly	Quantitative risk assessment
Water quality			
	Guideline values applied to water quality	Chemical constituents found in source waters	Periodic measurement of key chemical constituents to assess compliance with relevant guideline values (see section 8.5)
	Guideline values applied in testing procedures for materials and chemicals	Chemical additives and by-products	Testing procedures applied to the materials and chemicals to assess their contribution to drinking-water exposure taking account of variations over time (see section 8.5)
Performance			
	Generic performance target for removal of groups of microbes	Microbial contaminants	Compliance assessment through system assessment (see section 4.1) and operational monitoring (see section 4.2)
	Customized performance targets for removal of groups of microbes	Microbial contaminants	Individually reviewed by public health authority; assessment would then proceed as above
	Guideline values applied to water quality	Threshold chemicals with effects on health that vary widely (e.g., nitrate and cyanobacterial toxins)	Compliance assessment through system assessment (see section 4.1) and operational monitoring (see section 4.2)
Specified technology			
	National authorities specify specific processes to adequately address constituents with health effects (e.g., generic WSPs for an unprotected catchment)	Constituents with health effect in small municipalities and community supplies	Compliance assessment through system assessment (see section 4.1) and operational monitoring (see section 4.2)

Note: Each target type is based on those above it in this table, and assumptions with default values are introduced in moving down between target types. These assumptions simplify the application of the target and reduce potential inconsistencies.

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For chemical constituents of drinking-water, health-based targets can be developed using the guideline values outlined in section 8.5. These have been established on the basis of the health effect of the chemical in water. In developing national drinking-water standards (or health-based targets) based on these guideline values, it will be necessary to take into consideration a variety of environmental, social, cultural, economic, dietary and other conditions affecting potential exposure. This may lead to national targets that differ appreciably from the guideline values.

3.2.1 Specified technology targets

Specified technology targets are most frequently applied to small community supplies and to devices used at household level. They may take the form of recommendations concerning technologies applicable in certain circumstances and/or licensing programmes to restrict access to certain technologies or provide guidance for their application.

Smaller municipal and community drinking-water suppliers often have limited resources and ability to develop individual system assessments and/or management plans. National regulatory agencies may therefore directly specify requirements or approved options. This may imply, for example, providing guidance notes for protection of well heads, specific and approved treatment processes in relation to source types and requirements for protection of drinking-water quality in distribution.

In some circumstances, national or regional authorities may wish to establish model WSPs to be used by local suppliers either directly or with limited adaptation. This may be of particular importance when supplies are community managed. In these circumstances, an approach focusing on ensuring that operators receive adequate training and support to overcome management weaknesses is likely to be more effective than enforcement of compliance.

3.2.2 Performance targets

Performance targets are most frequently applied to the control of microbial hazards in piped supplies varying from small to large.

In situations where short-term exposure is relevant to public health, because water quality varies rapidly or it is not possible to detect hazards between production and consumption, it is necessary to ensure that control measures are in place and operating optimally and to verify their effectiveness in order to secure safe drinking-water.

Performance targets assist in the selection and use of control measures that are capable of preventing pathogens from breaching the barriers of source protection, treatment and distribution systems or preventing growth within the distribution system.

Performance targets should define requirements in relation to source water quality with prime emphasis on processes and practices that will ensure that the targets can be routinely achieved. Most commonly, targets for removal of pathogen groups through water treatment processes will be specified in relation to broad categories of

source water quality or source water type and less frequently in relation to specific data on source water quality. The derivation of performance targets requires the integration of factors such as tolerable disease burden (tolerable risk), including severity of disease outcomes and dose–response relationships for specific pathogens (target microbes) (see section 7.3).

Performance targets should be developed for target microbes representing groups of pathogens that combine both control challenges and health significance. In practice, more than one target microbe will normally be required in order to properly reflect diverse challenges to the safeguards available. While performance targets may be derived in relation to exposure to specific pathogens, care is required in relating this to overall population exposure and risk, which may be concentrated into short periods of time.

The principal practical application of performance targets for pathogen control is in assessing the adequacy of drinking-water treatment infrastructure. This is achieved by using information on performance targets with either specific information on treatment performance or assumptions regarding performance of technology types concerning pathogen removal. Examples of performance targets and of treatment effects on pathogens are given in chapter 7.

Performance requirements are also important in certification of devices for drinking-water treatment and for pipe installation that prevents ingress. Certification of devices and materials is discussed elsewhere (see section 1.2.9).

3.2.3 Water quality targets

Adverse health consequences may arise from exposure to chemicals following long-term and, in some cases, short-term exposure. Furthermore, concentrations of most chemicals in drinking-water do not normally fluctuate widely over short periods of time. Management through periodic analysis of drinking-water quality and comparison with WQTs such as guideline values is therefore commonly applied to many chemicals in drinking-water where health effects arise from long-term exposure. While a preventive management approach to water quality should be applied to all drinking-water systems, the guideline values for individual chemicals described in section 8.5 provide health-based targets for chemicals in drinking-water.

Where water treatment processes have been put in place to remove specific chemicals (see section 8.4), WQTs should be used to determine appropriate treatment requirements.

It is important that WQTs are established only for those chemicals that, following rigorous assessment, have been determined to be of health concern or of concern for the acceptability of the drinking-water to consumers. There is little value in undertaking measurements for chemicals that are unlikely to be in the system, that will be present only at concentrations much lower than the guideline value or that have no human health effects or effects on drinking-water acceptability.

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WQTs are also used in the certification process for chemicals that occur in water as a result of treatment processes or from materials in contact with water. In such applications, assumptions are made in order to derive standards for materials and chemicals that can be employed in their certification. Generally, allowance must be made for the incremental increase over levels found in water sources. For some materials (e.g., domestic plumbing), assumptions must also account for the relatively high release of some substances for a short period following installation.

For microbial hazards, WQTs in terms of pathogens serve primarily as a step in the development of performance targets and have no direct application. In some circumstances, especially where non-conventional technologies are employed in large facilities, it may be appropriate to establish WQTs for microbial contaminants.

3.2.4 Health outcome targets

In some circumstances, especially where there is a measurable burden of water-related disease, it is possible to establish a health-based target in terms of a quantifiable reduction in the overall level of disease. This is most applicable where adverse effects soon follow exposure and are readily and reliably monitored and where changes in exposure can also be readily and reliably monitored. This type of health outcome target is therefore primarily applicable to microbial hazards in both developing and developed countries and to chemical hazards with clearly defined health effects largely attributable to water (e.g., fluoride).

In other circumstances, health-based targets may be based on the results of quantitative risk assessment. In these cases, health outcomes are estimated based on information concerning exposure and dose–response relationships. The results may be employed directly as a basis to define WQTs or may provide the basis for development of performance targets.

There are limitations in the available data and models for quantitative microbial risk assessment (QMRA). Short-term fluctuations in water quality may have a major impact on overall health risks – including those associated with background rates of disease and outbreaks – and are a particular focus of concern in expanding application of QMRA. Further developments in these fields will significantly enhance the applicability and usefulness of this approach.

3.3 General considerations in establishing health-based targets

While water can be a major source of enteric pathogens and hazardous chemicals, it is by no means the only source. In setting targets, consideration needs to be given to other sources of hazards, including food, air and person-to-person contact, as well as the impact of poor sanitation and personal hygiene. There is limited value in establishing a strict target concentration for a chemical if drinking-water provides only a small proportion of total exposure. The cost of meeting such targets could unnecessarily divert funding from other, more pressing health interventions. It is important

to take account of the impact of the proposed intervention on overall rates of disease. For some pathogens and their associated diseases, interventions in water quality may be ineffective and may therefore not be justified. This may be the case where other routes of exposure dominate. For others, long experience has shown the effectiveness of drinking-water supply and quality management (e.g., typhoid, dysentery caused by *Shigella*).

Health-based targets and water quality improvement programmes in general should also be viewed in the context of a broader public health policy, including initiatives to improve sanitation, waste disposal, personal hygiene and public education on mechanisms for reducing both personal exposure to hazards and the impact of personal activity on water quality. Improved public health, reduced carriage of pathogens and reduced human impacts on water resources all contribute to drinking-water safety (see Howard et al., 2002).

3.3.1 Assessment of risk in the framework for safe drinking-water

In the framework for safe drinking-water, assessment of risk is not a goal in its own right but is part of an iterative cycle that uses the assessment of risk to derive management decisions that, when implemented, result in incremental improvements in water quality. For the purposes of these Guidelines, the emphasis of incremental improvement is on health. However, in applying the Guidelines to specific circumstances, non-health factors should be taken into account, as they may have a considerable impact upon both costs and benefits.

3.3.2 Reference level of risk

Descriptions of a “reference level of risk” in relation to water are typically expressed in terms of specific health outcomes – for example, a maximum frequency of diarrhoeal disease or cancer incidence or maximum frequency of infection (but not necessarily disease) with a specific pathogen.

There is a range of water-related illnesses with differing severities, including acute, delayed and chronic effects and both morbidity and mortality. Effects may be as diverse as adverse birth outcomes, cancer, cholera, dysentery, infectious hepatitis, intestinal worms, skeletal fluorosis, typhoid and Guillain-Barré syndrome.

Decisions about risk acceptance are highly complex and need to take account of different dimensions of risk. In addition to the “objective” dimensions of probability, severity and duration of an effect, there are important environmental, social, cultural, economic and political dimensions that play important roles in decision-making. Negotiations play an important role in these processes, and the outcome may very well be unique in each situation. Notwithstanding the complexity of decisions about risk, there is a need for a baseline definition of tolerable risk for the development of guidelines and as a departure point for decisions in specific situations.

A reference level of risk enables the comparison of water-related diseases with one another and a consistent approach for dealing with each hazard. For the purposes of

these Guidelines, a reference level of risk is used for broad equivalence between the levels of protection afforded to toxic chemicals and those afforded to microbial pathogens. For these purposes, only the health effects of waterborne diseases are taken into account. The reference level of risk is 10^{-6} disability-adjusted life-years (DALYs) per person per year, which is approximately equivalent to a lifetime excess cancer risk of 10^{-5} (i.e., 1 excess case of cancer per 100 000 of the population ingesting drinking-water containing the substance at the guideline value over a life span) (see section 3.3.3 for further details). For a pathogen causing watery diarrhoea with a low case fatality rate (e.g., 1 in 100 000), this reference level of risk would be equivalent to 1/1000 annual risk of disease to an individual (approximately 1/10 over a lifetime). The reference level of risk can be adapted to local circumstances on the basis of a risk–benefit approach. In particular, account should be taken of the fraction of the burden of a particular disease that is likely to be associated with drinking-water. Public health prioritization would normally indicate that major contributors should be dealt with preferentially, taking account of the costs and impacts of potential interventions. This is also the rationale underlying the incremental development and application of standards. The application of DALYs for setting a reference level of risk is a new and evolving approach. A particular challenge is to define human health effects associated with exposure to non-threshold chemicals.

3.3.3 Disability-adjusted life-years (DALYs)

The diverse hazards that may be present in water are associated with very diverse adverse health outcomes. Some outcomes are acute (diarrhoea, methaemoglobinemia), and others are delayed (cancer by years, infectious hepatitis by weeks); some are potentially severe (cancer, adverse birth outcomes, typhoid), and others are typically mild (diarrhoea and dental fluorosis); some especially affect certain age ranges (skeletal fluorosis in older adults often arises from exposure in childhood; infection with hepatitis E virus [HEV] has a very high mortality rate among pregnant women), and some have very specific concern for certain vulnerable subpopulations (cryptosporidiosis is mild and self-limiting for the population at large but has a high mortality rate among those who test positive for human immunodeficiency virus [HIV]). In addition, any one hazard may cause multiple effects (e.g., gastroenteritis, Guillain-Barré syndrome, reactive arthritis and mortality associated with *Campylobacter*).

In order to be able to objectively compare water-related hazards and the different outcomes with which they are associated, a common “metric” that can take account of differing probabilities, severities and duration of effects is needed. Such a metric should also be applicable regardless of the type of hazard, applying to microbial, chemical and radiological hazards. The metric used in the *Guidelines for Drinking-water Quality* is the DALY. WHO has quite extensively used DALYs to evaluate public health priorities and to assess the disease burden associated with environmental exposures.

The basic principle of the DALY is to weight each health effect for its severity from 0 (normal good health) to 1 (death). This weight is multiplied by the duration of the effect – the time in which disease is apparent (when the outcome is death, the “duration” is the remaining life expectancy) – and by the number of people affected by a particular outcome. It is then possible to sum the effects of all different outcomes due to a particular agent.

Thus, the DALY is the sum of years of life lost by premature mortality (YLL) and years of healthy life lost in states of less than full health, i.e., years lived with a disability (YLD), which are standardized by means of severity weights. Thus:

$$\text{DALY} = \text{YLL} + \text{YLD}$$

Key advantages of using DALYs are its “aggregation” of different effects and its combining of quality and quantity of life. In addition – and because the approaches taken require explicit recognition of assumptions made – it is possible to discuss these and assess the impact of their variation. The use of an outcome metric also focuses attention on actual rather than potential hazards and thereby promotes and enables rational public health priority setting. Most of the difficulties in using DALYs relate to availability of data – for example, on exposure and on epidemiological associations.

DALYs can also be used to compare the health impact of different agents in water. For example, ozone is a chemical disinfectant that produces bromate as a by-product. DALYs have been used to compare the risks from *Cryptosporidium parvum* and bromate and to assess the net health benefits of ozonation in drinking-water treatment.

In previous editions of the *Guidelines for Drinking-water Quality* and in many national drinking-water standards, a “tolerable” risk of cancer has been used to derive guideline values for non-threshold chemicals such as genotoxic carcinogens. This is necessary because there is some (theoretical) risk at any level of exposure. In this and previous editions of the Guidelines, an upper-bound excess lifetime risk of cancer of 10^{-5} has been used, while accepting that this is a conservative position and almost certainly overestimates the true risk.

Different cancers have different severities, manifested mainly by different mortality rates. A typical example is renal cell cancer, associated with exposure to bromate in drinking-water. The theoretical disease burden of renal cell cancer, taking into account an average case:fatality ratio of 0.6 and average age at onset of 65 years, is 11.4 DALYs per case (Havelaar et al., 2000). These data can be used to assess tolerable lifetime cancer risk and a tolerable annual loss of DALYs. Here, we account for the lifelong exposure to carcinogens by dividing the tolerable risk over a life span of 70 years and multiplying by the disease burden per case: (10^{-5} cancer cases / 70 years of life) \times 11.4 DALYs per case = 1.6×10^{-6} DALYs per person-year or a tolerable loss of 1.6 healthy life-years in a population of a million over a year.

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For guideline derivation, the preferred option is to define an upper level of tolerable risk that is the same for exposure to each hazard (contaminant or constituent in water). As noted above, for the purposes of these Guidelines, the reference level of risk employed is 10^{-6} DALYs per person-year. This is approximately equivalent to the 10^{-5} excess lifetime risk of cancer used in this and previous editions of the Guidelines to determine guideline values for genotoxic carcinogens. For countries that use a stricter definition of the level of acceptable risk of carcinogens (such as 10^{-6}), the tolerable loss will be proportionately lower (such as 10^{-7} DALYs per person-year).

Further information on the use of DALYs in establishing health-based targets is included in the supporting document *Quantifying Public Health Risk in the WHO Guidelines for Drinking-water Quality* (see section 1.3).