World Health Organization

Results of Round I

of the WHO International Scheme to Evaluate Household Water Treatment Technologies

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Contents

Abbreviations and acronyms . . . 3

Acknowledgements . . . 4

Executive summary . . . 6

Background . . . 10

1. Round I of the Scheme . . . 13
1.1 An overview of the Scheme . . . 13
1.1.1 HWT performance targets . . . 14
1.1.2 The Scheme evaluation procedure . . . 15
1.1.3 Quality assurance . . . 16
1.1.4 Overview of the product testing . . . 17
1.2 HWT products evaluated in Round I . . . 19
1.3 Results . . . 35
1.3.1 Microbiological performance of HWT products . . . 35
1.3.2 Findings from the reviews of product information and existing data . . . 37
1.3.3 Interpretation of evaluation results . . . 38
1.3.4 Use of results in selecting HWT products . . . 38
1.4 Global distribution of products evaluated . . . 39

2. Implications: supporting availability and scaling up of quality HWT and safe storage . . . 41
2.1 Rapid market assessment . . . 41
2.1.1 Sub-Saharan Africa: Estimated use and regulation of HWT . . . 42
2.1.2 Asia: Estimated use and regulation of HWT . . . 43
2.2 Scaling up use of quality assured HWT products . . . 43
2.2.1 Strengthening regulations . . . 44
2.2.2 Increasing availability of quality HWT products . . . 44
2.2.3 Supporting the broader enabling environment . . . 45

3. Conclusion and lessons learned . . . 47

References . . . 48

Annexes . . . 50
Annex 1: The Scheme evaluation procedure . . . 50
Annex 2: Overview of reported use of HWT in selected countries in Sub-Saharan Africa and Asia . . . 54
Annex 3: Overview of the regulatory environment for HWT . . . 55

List of figures

Figure 1. Estimated reductions in diarrhoeal disease from household water treatment . . . 10
Figure 2. The Scheme components . . . 13
Figure 3. Overview of the Scheme evaluation procedure . . . 16
Figure 4. Performance classification of HWT technologies evaluated in Round I . . . 35
Figure 5. Log_{10} reduction of bacteria, viruses and protozoa met or exceeded by products evaluated in Round I . . . 36
Figure 6. Global reach of the HWT products evaluated in Round I . . . 39
Figure 7. Percentage of the population reporting HWT, by WHO region . . . 41
Figure A.1 Overview of the Scheme testing protocols . . . 52

List of tables

Table 1. Performance classification of products found to meet WHO performance criteria in Round I . . . 7
Table 2. WHO recommended microbiological performance criteria for HWT technology performance classification . . . 14
Table 3. Products evaluated in Round I of the Scheme . . . 19
Table A.1 Test organisms of the Scheme . . . 52
Table A.2 Characteristics of general and challenge test waters . . . 53
Table A.3 Use of HWT in selected countries – Sub-Saharan Africa . . . 54
Table A.4 Use of HWT in selected Asian countries . . . 54
Table A.5 Overview of the regulatory environment for HWT in selected countries in Sub-Saharan Africa . . . 55
Table A.6 Overview of the regulatory environment for HWT in selected countries in Asia . . . 56

List of boxes

Box 1. Boiling remains the most commonly reported method of household water treatment . . . 9
Box 2. Importance of safe storage . . . 11
Box 3. Quantitative microbial risk assessment . . . 14
Box 4. Log_{10} reduction . . . 14
Box 5. Technologies providing 'targeted protection' and the multi-barrier approach . . . 15
Box 6. Reliability of testing between the designated laboratories . . . 17
Box 7. Household water treatment in emergencies . . . 38
Box 8. Selecting HWT products . . . 39
Box 9. Strengthening regulation in Ethiopia . . . 42
Box 10. Supporting implementation of a national HWT Strategy in Ghana . . . 42
Box 11 . Rising filter markets and public-private partnerships in Viet Nam . . . 43
Box 12. Consumer demand for HWT regulation in India . . . 43
Box 13. WHO/UNICEF International Network on Household Water Treatment and Safe Storage: working to increase health gains from HWTS . . . 44
Box 14. Strengthening testing of local products in Ethiopia . . . 44
Box 15. Strengthening manufacture of quality local products . . . 45
Box 16. Smart subsidies in HWT . . . 45
Box 17. Supporting countries in creating enabling environments for HWT and safe storage . . . 46

Abbreviations and acronyms

ATCC	American Type Culture Collection
BSF	biosand filter
EOI	expression of interest
GDWQ	Guidelines for Drinking-water Quality
HWT	household water treatment
IAC	independent advisory committee
ISO	International Organization for Standardization
KWR	KWR Watercycle Institute
L	litre
NSF	NSF International
PET	polyethylene terephthalate
QMRA	quantitative microbial risk assessment
Scheme	WHO International Scheme To Evaluate Household Water Treatment Technologies
UN	United Nations
UNICEF	United Nations Children's Fund
UV	ultraviolet
WASH	water, sanitation and hygiene
WHO	World Health Organization
WSP	water safety plan

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Executive summary

Globally, an estimated 1.9 billion people use either an unimproved water source or an improved source[1] that is faecally-contaminated. Furthermore, 502,000 diarrhoeal deaths in low- and middle-income countries can be attributed to insufficient and unsafe drinking-water (WHO, 2014a). The vast majority of these deaths occur in Africa and South-East Asia, mainly among vulnerable populations, including young children, the malnourished and people living with the human immunodeficiency virus.

The 2030 Sustainable Development Agenda agreed by United Nations (UN) Member States in 2015 calls for universal access to safe drinking water, and the proposed indicator of 'safely managed drinking-water services' will require direct measurement of drinking-water quality (WHO/UNICEF, 2015a). Improved protection and management of drinking-water supplies, including at the household level, will therefore gain increasing importance for achieving the new Sustainable Development Goal targets. Long-term, this can be achieved through increased use of risk management approaches like Water Safety Planning, but in the short and medium term household water treatment (HWT) and safe storage can play an important role.

1 Unimproved sources of drinking-water include surface water, unprotected springs and unprotected dug wells. Full definitions of improved and unimproved sources can be found at: http://www.wssinfo.org/definitions-methods/watsan-categories/

TABLE 1

Performance classification of products found to meet WHO performance criteria in Round I

Technology	Product	Manufacturer	Performance target met	Performance classification (assuming correct and consistent use)
Membrane ultrafiltration	LifeStraw Family 1.0	LifeStraw SA	★★★	Comprehensive protection: *very high removal of bacteria, viruses and protozoa*
Membrane ultrafiltration	LifeStraw Community	LifeStraw SA	★★★	
Membrane ultrafiltration	LifeStraw Family 2.0	LifeStraw SA	★★	Comprehensive protection: *high removal of bacteria, viruses and protozoa*
Flocculation-disinfection	P&G Purifier of Water	The Procter & Gamble Company	★★	
UV disinfection	Waterlogic Hybrid / Edge Purifier	Qingdao Waterlogic Manufacturing Company	★★	
Chemical disinfection	Aquatabs	Medentech Limited	★	Targeted protection: *removal of bacteria and viruses only*
Chemical disinfection	H2gO Purifier	Aqua Research LLC	★	
Solar disinfection	WADI	Helioz GmbH	★	Targeted protection: *removal bacteria and protozoa only*

★★★: removes at least 4 $\log_{10}$ of bacteria, at least 5 $\log_{10}$ of viruses and at least 4 $\log_{10}$ of protozoa
★★: removes at least 2 $\log_{10}$ of bacteria, at least 3 $\log_{10}$ of viruses and at least 2 $\log_{10}$ of protozoa
★: meets the performance targets for at least 2-star (★★) for *only two* classes of pathogens

HWT and safe storage is an important public health intervention to improve the quality of drinking-water and prevent waterborne disease. However, achieving health gains associated with HWT relies on two important factors. HWT technologies need to sufficiently reduce pathogens to protect health and also to be used correctly and consistently by those who are exposed to contaminated water. The first of these conditions – microbiological performance – is critical, and is the primary focus of this report.

The International Scheme to Evaluate Household Water Treatment Technologies (the Scheme) was established by the World Health Organization (WHO) in 2014 to evaluate the microbiological performance of HWT technologies against WHO health-based criteria. The results of the Scheme evaluation are intended to guide HWT product selection by Member States and procuring UN agencies. In this regard, the Scheme fills an important global and national need for independent health-based evaluation of HWT, especially considering the large number of product manufacturers and product claims, and the limited capacity of low-income countries to conduct testing to verify these claims.

This *Round I Report* of the Scheme is the first ever global assessment of HWT performance, and details the results from a range of HWT technologies including solar, chemical, filtration and ultraviolet (UV). In addition, the report draws on the findings from a rapid assessment of the HWT product market and enabling environment in Africa and South-East Asia. The report:

- highlights that performance is a fundamental criterion in HWT product selection, and a number of products are available that were found to meet WHO recommended performance targets;
- draws attention to the fact that, despite the significant need for effective HWT solutions among vulnerable populations, product evaluation and regulation is generally weak; and
- recommends specific actions at the national level needed to ensure that health gains from HWT are realized; these include strengthening product regulation and enabling environments for HWT, understanding market development and user needs and motivations for sustained use.

The report is divided into two main sections. Section 1 summarizes the results of *Round I* of the Scheme evaluations, performed in 2014/2015, with data on the performance of ten HWT products. The performance of HWT products is classified as 3-star (★★★); 2-star (★★); and 1-star (★), denoting descending order of performance, based on $\log_{10}$ reductions of bacteria, viruses and protozoa from drinking-water. Performance that does not meet the minimum target is given no stars. The results of the performance testing and review of existing data and product information highlight that:

- **A variety of HWT products are available that were found to meet WHO recommended performance targets.** Of the ten products evaluated, five were found to provide comprehensive protection against all three classes of pathogens (3-star or 2-star), while three were found to provide targeted protection against two of the three classes of pathogens (1-star). The eight products found to meet WHO recommended performance targets are listed in Table 1.

- **Some products fail to meet the Scheme's minimum standard of health protection.** Two of the products evaluated do not meet the Scheme's minimum microbiological performance criteria. Identifying such products is crucial to inform appropriate HWT product selection and procurement and to promote use of better performing alternatives. Information on these products is provided in Section 1.3.1 of this report.

- **Awareness of the key considerations in HWT performance evaluation is limited.** Three main findings arising from the review of existing testing data and discussions with HWT stakeholders are that:
  - **Performance is often overlooked in selecting products.** Both products that did not meet the performance criteria were being distributed or sold on the market at the time of testing. While WHO recognizes that microbiological performance is only one of many factors to consider, this performance is a prerequisite for health gains.
  - **Testing conducted outside the Scheme is undertaken with varying methods and often under "ideal" conditions** such as using non-turbid water, high doses and long contact times, and only against a limited set of parameters. This results in data which only reflect "part of" HWT performance, rather than comprehensive data under all conditions, thus rendering interpretation of tests difficult and comparability between tests even more so.
  - **Product information, including use instructions and labelling can be unclear**, and deciphering information that is pertinent to product performance is difficult. Without sufficient product information, the ability of users to correctly and consistently use HWT and ultimately achieve health gains is compromised.

Section 2 outlines the main findings from the rapid market assessment of HWT in Africa and Asia, and discusses key scaling up efforts required to better monitor, target and understand the use of quality HWT. While the limited scope of the assessment precludes making definitive statements about the HWT market in these regions, the available data from selected countries provide some useful insights on the HWT environment. The findings highlight that:

- **There is a strong growth in filter markets in parts of Asia.** While boiling remains the most commonly reported method of HWT (Box 1), filtration is increasingly common in Asia. Findings from India, Viet Nam, China and South Korea highlight that the growth in the filter markets is likely attributed to growing consumer awareness of a number of factors, including the quality of supplied water, the potential health gains from using HWT, the wide availability of HWT products and also the ability of middle-income households to pay.

BOX 1

Boiling remains the most commonly reported method of household water treatment

Boiling is reported by approximately one fifth of households in low- and middle-income countries. It is very effective in inactivating waterborne pathogens, including bacteria, viruses and protozoa. However, an important limitation is that the treated water may be susceptible to recontamination due to unsafe storage and handling after boiling (WHO, 2015a). In addition, use of certain fuels and stoves has adverse environmental consequences, including contributing to climate change. As with other household water treatment methods, actual use of boiling may be lower than self-reported use, and consequently its health impact may be limited in practice (Brown and Sobsey, 2012; Rosa et al., 2014).

- **Behavioural interventions and understanding of consumer preferences are necessary to realize sustained use of HWT.**
  The vast majority of those without improved water sources live in sub-Saharan Africa, and an estimated 53% of the population in the region are exposed to water that is faecally-contaminated (WHO, 2014a). Yet, reported HWT use in the region remains relatively low (20 %, on average). Implementation of HWT is largely project-based and is often focused on emergency relief efforts or cholera outbreaks, highlighting the need for approaches that promote more sustained, ongoing use and develop the mechanisms and systems to ensure availability, user support and effective supply chains.

- **Regulation of HWT is weak and fragmented.**
  Findings from Ethiopia, Ghana and Viet Nam highlight that regulatory frameworks for HWT products are weak, and often fragmented. Overall, few countries regulate HWT products based on their microbiological performance, and among those that do, such regulation is often limited to chemical disinfectants and performance testing, at best, only includes faecal indicator bacteria, rather than all three classes of pathogens.

The section concludes with three main priorities to support scaling up of quality assured HWT products. These priorities are:

- **Strengthening the regulatory capacity of national governments**, through increasing awareness of the WHO HWT performance criteria, and strengthening the capacity of national regulatory institutions to conduct complimentary evaluations of HWT and evaluate product efficacy data and certifications.

- **Strengthening local manufacturing of quality HWT products,** by supporting implementation of best manufacturing practices tools. This includes developing a better understanding of the key variants affecting performance of locally manufactured HWT products, and strengthening quality assurance and quality control at local manufacturing plants through implementation of best manufacturing practices tools.

- **Strengthening implementation of HWT** to ensure that effective HWT products reach, and are used correctly and consistently by, those most at risk of waterborne disease. This requires effective targeting of market development, understanding of consumer preferences, behavioural interventions and monitoring and evaluating ongoing use and smarter HWT implementation for better health impact.

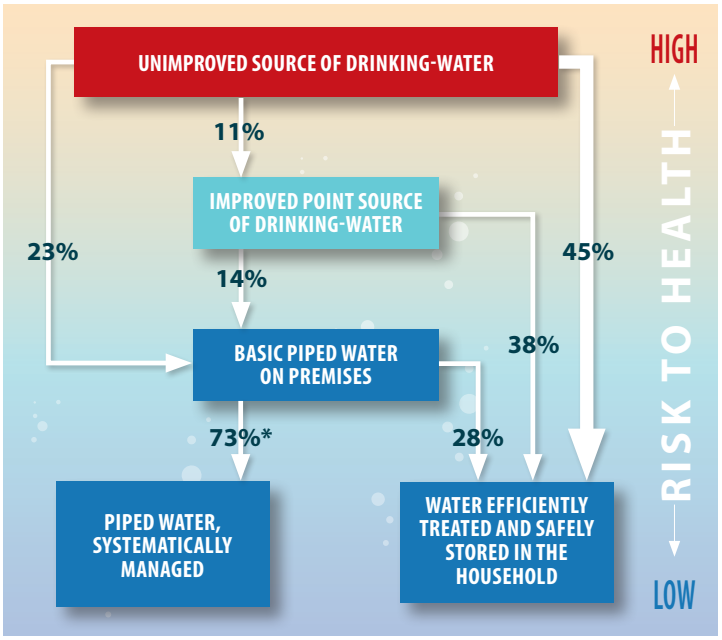
Background

An estimated 842,000 deaths each year are attributable to inadequate water, sanitation and hygiene; representing 58% of the total diarrhoeal deaths in low- and middle-income countries. Furthermore, unsafe and insufficient drinking-water account for an estimated 502,000 diarrhoea deaths in low and middle-income countries (WHO, 2014a). Many of these deaths could be prevented by improving the quality of drinking-water. In particular, the use of a comprehensive risk assessment and management approach, known as a water safety plan (WSP) will support consistent good quality water (WHO, 2009). Household water treatment (HWT) and safe storage is one particular control option within a broader WSP to make water safer to drink (WHO, 2011b).

HWT and safe storage is not a substitute for sustainable access to safe drinking-water, but does serve as an important interim measure for removing pathogens from drinking-water and reducing disease risk, particularly for the 663 million individuals (WHO/UNICEF, 2015b) who do not have access to improved supplies. Furthermore, when safety (as defined by faecal contamination) is considered, the number of individuals in need of safer water increases to 1.9 billion (WHO, 2014a).

Achieving health gains associated with HWT and safe storage depends on two key requirements. First, HWT technologies must be microbiologically effective; i.e. they must sufficiently reduce pathogens to protect health. Second, such technologies must reach, and be consistently and correctly used by, the groups most at risk for waterborne disease. This requires consideration of a number of key factors such as effective supply chains, affordability, user preferences and changing and sustaining user behaviour. When effective methods are used correctly and consistently, HWT and safe storage can reduce diarrhoeal disease by as much as 45 % (Figure 1). While the focus of this report is on water treatment technologies and thus the use of HWT, it is important to note that safe storage is critical to keeping water safe after collection and or treatment (Box 2).

FIGURE 1
Estimated reductions in diarrhoeal disease from household water treatment (WHO, 2014a)



* The estimates are based on limited evidence and should therefore be considered as preliminary

BOX 2
Importance of safe storage

Studies have shown that safe storage alone can significantly reduce diarrhoeal disease (Roberts et al., 2001) which highlights the importance and the cost-effectiveness of this measure. Increasingly a number of HWT products incorporate safe storage into their design (as is often the case for filters) or through the presence of a chlorine residual. With climate change and increasing fluctuations in water supply and the resulting need to store water in the household, safe storage is likely to become even more important in the future. Furthermore, safe storage is also associated with other health benefits beyond diarrhoeal disease reduction, such as decreasing the risk of dengue by reducing breeding grounds for the mosquito vector.

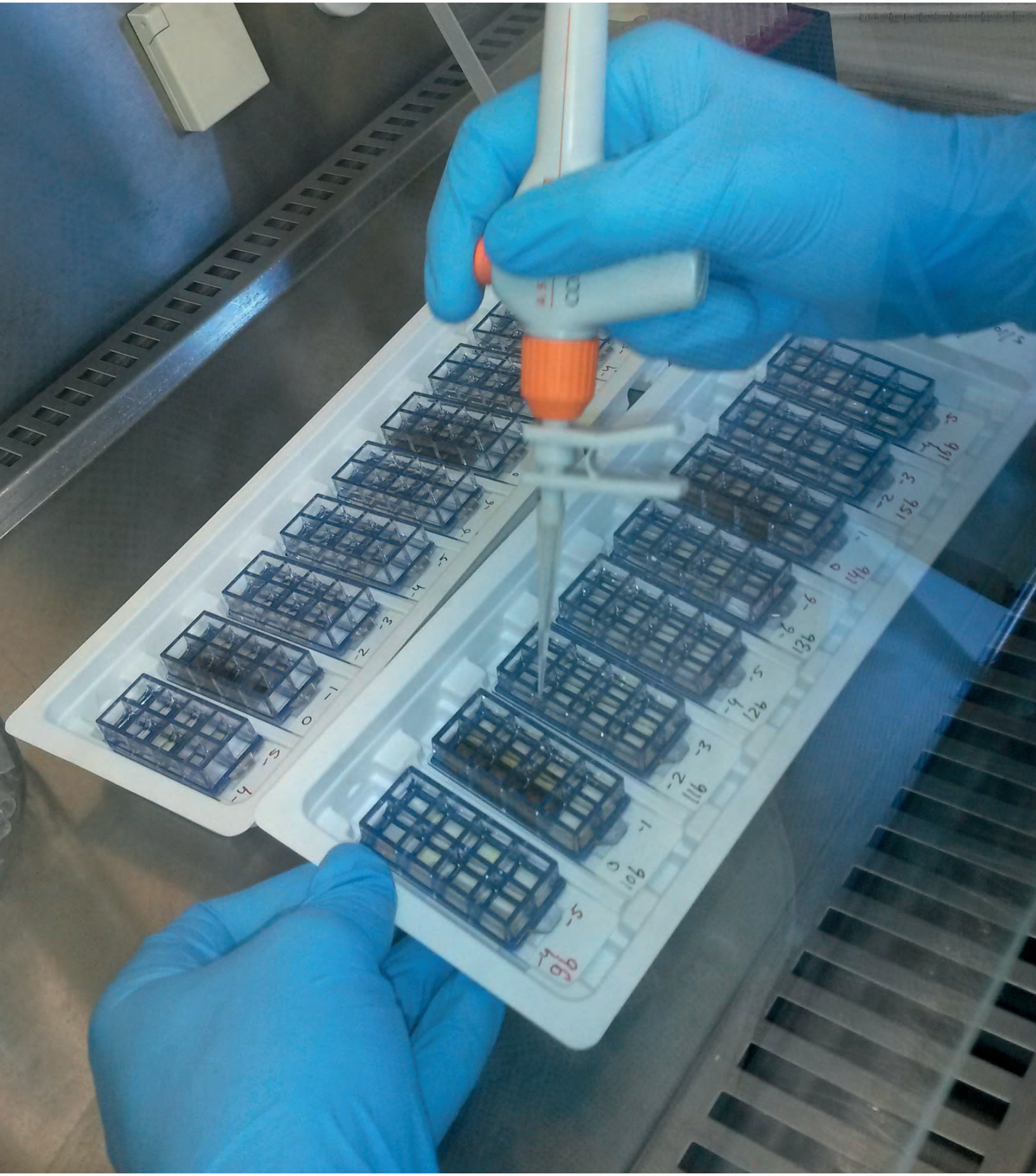
There are a number of different HWT methods. The main types include chemical disinfection, disinfection with heat or ultraviolet (UV), filtration and flocculation-disinfection. In order to comprehensively assess effectiveness, the World Health Organization (WHO) has recommended health-based performance targets for HWT products based on the removal of enteric bacteria, viruses, and protozoa[1] (WHO, 2011a). However, many low- and middle-income countries have neither the capacity, nor the resources to evaluate technologies based on WHO recommendations. Concurrently, these same governments – mainly located in Sub-Saharan Africa, South-East Asia and parts of Central and South America – are increasingly being approached by manufacturers to buy and allow the sale of their products within the respective countries. To this end, in 2014 WHO established the International Scheme to Evaluate Household Water Treatment Technologies (the Scheme) to independently and consistently evaluate HWT products based on specific performance criteria that address the removal of viruses, bacteria and protozoa (WHO, 2011a). The objectives of the Scheme are to:

- promote and coordinate independent and consistent evaluation of HWT based on WHO recommended criteria and, in so doing, guide WHO Member States and procuring United Nations agencies in the selection of HWT; and

- support governments in a number of evaluation-related functions, including building technical capacity of research institutions, conducting complimentary national assessments of HWT in the field, and strengthening national regulation of HWT.

Together, these two objectives and the associated activities serve the ultimate aim of the Scheme, which is to reduce the burden of disease associated with unsafe drinking-water.

1 Performance testing of HWT technologies under the Scheme currently does not specifically address non-enteric pathogens that may grow in household water systems when warm water is stored (Ashbolt, 2015), nor non-microbial contaminants such as arsenic and fluoride.



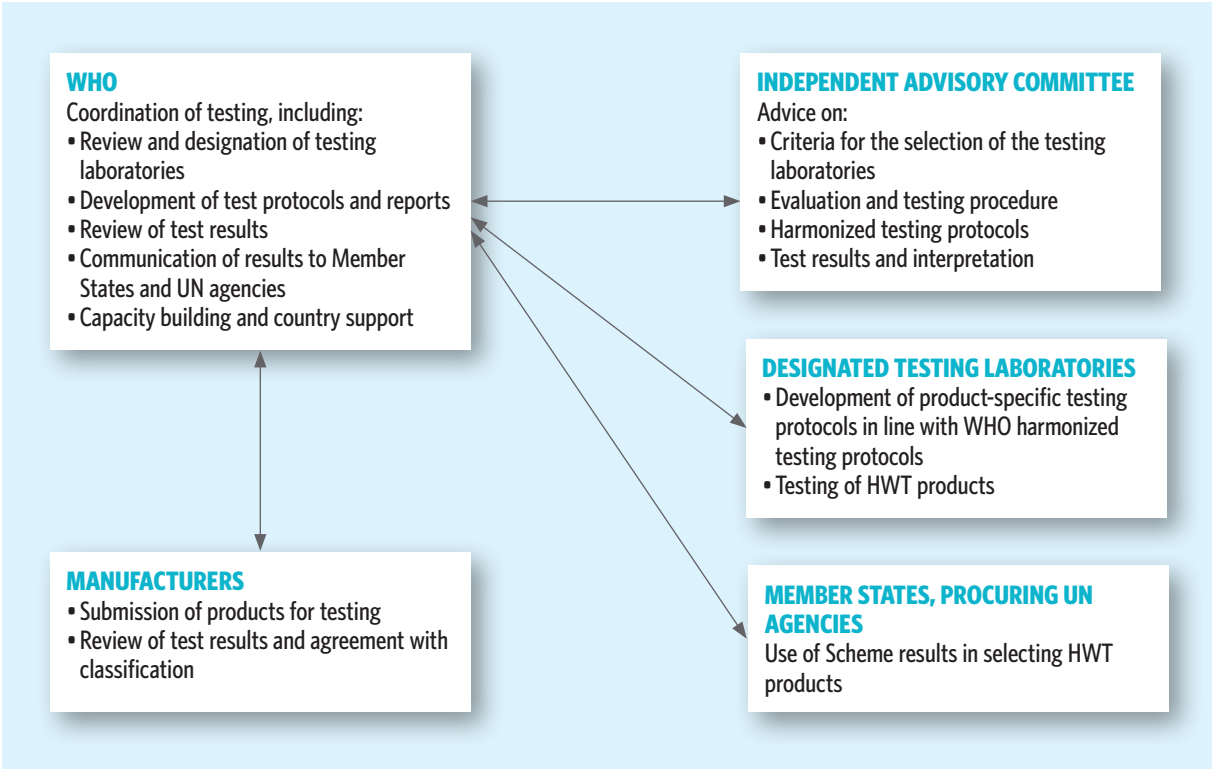
1. Round I of the Scheme

1.1 An overview of the Scheme

The Scheme is coordinated by the Water, Sanitation, Hygiene and Health Unit at the WHO. In this role, WHO reviews and designates testing laboratories, develops testing protocols and report templates, coordinates the testing of technologies, reviews testing results and communicates the test results to Member States (Figure 2).

WHO works with an independent advisory committee (IAC) of experts in drinking-water treatment, microbiology and epidemiology[1], and designated testing laboratories to independently evaluate the performance of submitted HWT products. The highly specialized technical nature of evaluating HWT technologies necessitates testing in laboratories with advanced capabilities. Thus, laboratories need to have systems in place to ensure the integrity of testing and the results, including compliance with the quality management requirements of the International Organization for Standardization (ISO) 17025. There are currently two laboratories that have been designated to conduct testing[2]. These are KWR Watercycle Research Institute (KWR) in the Netherlands and NSF International (NSF) in the United States of America.

FIGURE 2
The Scheme components



1 Terms of reference for the IAC can be found at: http://www.who.int/household_water/scheme/IAC/en/

2 The criteria applied in the selection of the testing laboratories can be found at: http://www.who.int/household_water/scheme/laboratories/en/

1.1.1 HWT performance targets

The evaluation of HWT technologies is based on the recommended performance criteria set out in *Evaluating household water treatment options: health-based targets and microbiological performance specifications* (WHO, 2011a). These criteria were determined by applying the concept of tolerable burden of disease (acceptable risk) as outlined in the fourth edition of the GDWQ (WHO, 2011b). Using quantitative microbial risk assessment (QMRA) methods described in the GDWQ (Box 3), and assuming background levels of reference pathogens in untreated water, reductions of pathogens were calculated to meet risk-based targets.

BOX 3
Quantitative microbial risk assessment

Quantitative microbial risk assessment (QMRA) is the process of estimating the risk posed to human health from exposure to microbial pathogens. The process uses data on source water quality, effectiveness of treatment and characteristics of microbial pathogens, to estimate the disease burden associated with exposure to pathogens in drinking-water.

From this, three categories of recommended performance: 3-star (★★★); 2-star (★★); and 1-star (★), were developed, denoting descending order of performance[1]. The performance targets pertain to three main classes of pathogens which cause enteric infections and disease, namely bacteria, viruses and protozoa. The $\log_{10}$ reductions required to achieve the performance targets for each pathogen class are presented in Table 2, and a description of a log reductions is provided in Box 4.

TABLE 2
WHO recommended microbiological performance criteria for HWT technology performance classification

Performance classification	Bacteria ($\log_{10}$ reduction required)	Viruses ($\log_{10}$ reduction required)	Protozoa ($\log_{10}$ reduction required)	Interpretation (assuming correct and consistent use)
★★★	≥ 4	≥ 5	≥ 4	Comprehensive protection (very high pathogen removal)
★★	≥ 2	≥ 3	≥ 2	Comprehensive protection (high pathogen removal)
★	Meets at least 2-star (★★) criteria for two classes of pathogens			Targeted protection
–	Fails to meet WHO performance criteria			Little or no protection

BOX 4
$\log_{10}$ reduction

The microbiological performance of HWT technologies is often presented as a comparison of the concentration of pathogens in water before, and after treatment, on a logarithmic basis. A 1-log reduction stands for a ten-fold or 90% reduction in the concentration of pathogens in water.
- 1 $\log_{10}$ reduction = 90% reduction
- 2 $\log_{10}$ reduction = 99% reduction
- 3 $\log_{10}$ reduction = 99.9% reduction, etc.

1 The performance targets were originally labelled as Highly protective, Protective and Interim (WHO, 2011a). While the log reduction requirements remain the same, the nomenclature has been subsequently revised to the star rating, based on feedback from a strategic meeting held in March 2015, to be more universally understood.

These three pathogen classes occur widely in drinking-water supplies impacted by animal and/or human excreta. For example, in a recent global study involving over 20,000 children in seven developing countries, rotavirus, *Cryptosporidium* protozoa and some toxin-producing strains of the bacterium *Escherichia coli* (*E. coli*) were among the top pathogens associated with moderate to severe diarrhoea (Kotloff et al., 2013). In addition, increased *E. coli* contamination in household water has been associated with an increase in child diarrhoea (Luby et al., 2015). Thus, in many faecally-contaminated drinking-water sources it is important that HWT technologies sufficiently reduce all three classes of pathogens. Where such technologies are not available a multi-barrier approach is advised (Box 5). Within each class of pathogen, there are many different organisms associated with waterborne diseases and it is neither feasible nor practical to evaluate the performance of HWT technologies against each of them. Instead, reference organisms have been selected to represent the three classes. These reference organisms are: *E. coli* (bacteria), coliphages MS2 and phiX174 (viruses) and *Cryptosporidium parvum* (protozoa). An overview of the key considerations in selecting these reference organisms is given in Annex 1.

BOX 5
Technologies providing 'targeted protection' and the multi-barrier approach

The WHO recommends a multi-barrier approach to water safety, where combinations of technologies can be used to treat water. While technologies that provide targeted protection such as chlorine disinfectants are effective against only bacteria and viruses, they can be combined with a method that is effective against protozoa (such as filtration) to achieve comprehensive protection.

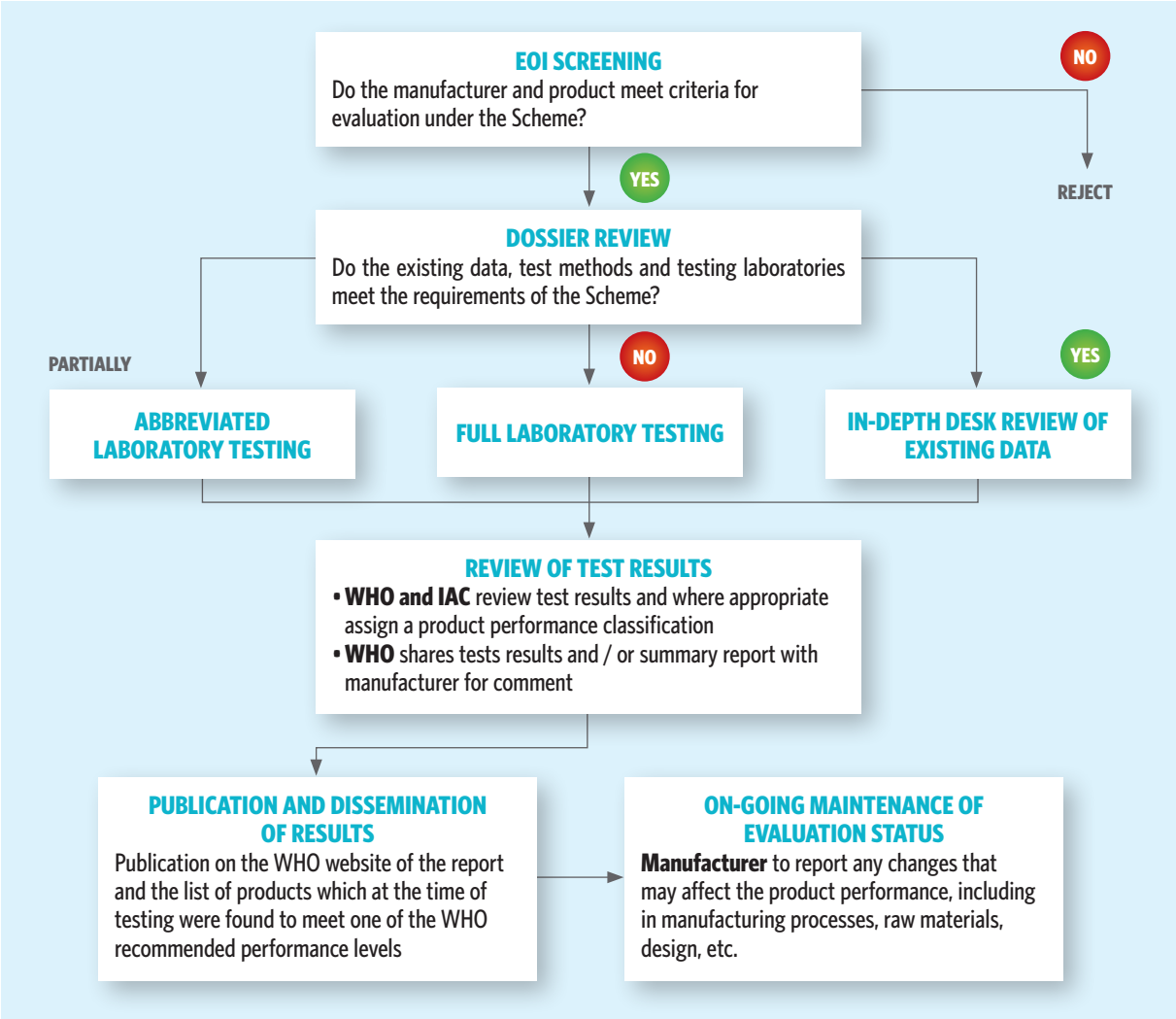
1.1.2 The Scheme evaluation procedure

Evaluation under the Scheme is based on the voluntary submission of an expression of interest (EOI) from manufacturers. Priority products for evaluation are those that are:

- low cost;
- appropriate for low-income settings;
- generally 'free-standing' and do not need to be plumbed in; and
- which only treat sufficient water to serve a limited number of individuals a day, as would be typically used in households or small public facilities such as tertiary healthcare centres.

Each EOI that meets these initial screening criteria is selected for review by the Scheme Secretariat at WHO with input and advice from the IAC. In its role as coordinator, WHO works with the IAC to review these submissions, develop testing protocols and manage communications and reporting with the designated testing laboratories and manufacturers (further details on the screening and evaluation criteria are outlined in Annex 1). The results of the evaluation are published on the WHO website. An overview of the Scheme evaluation procedure is shown in Figure 3. Evaluations are conducted according to standardized protocols in line with the above-mentioned performance criteria. The evaluation may consider existing data and abbreviated testing, in lieu of full testing, provided that such data have been generated by independent, highly qualified testing laboratories using quality assurance protocols that are similar to those of the Scheme

FIGURE 3
Overview of the Scheme evaluation procedure



1.1.3 Quality assurance

Quality assurance elements in place to provide appropriate and consistent evaluation of HWT technologies include harmonized testing protocols, ongoing learning exchange and site visits between highly qualified laboratories and regular review of evidence to ensure testing is in line with latest science.

The testing procedures

To ensure appropriate and consistent evaluation across products and technologies, product testing follows a harmonized testing protocol, based on internationally recognized performance approaches and recommendations by the IAC. The protocol is intentionally prescriptive to ensure consistency in evaluation and it outlines:

- the specifications for each test water characteristic, the adjustment materials to be used and the published methods of analysis to be used to verify and report compliance with the specifications; and

- the Scheme reference target organisms to be used, which are well documented as laboratory test microorganisms. Where appropriate, internationally recognized identifications are used such as the American Type Culture Collection (ATCC), and testing utilizes the production and assay procedures outlined in the harmonized testing protocol. Collection procedures, including neutralization details, storage conditions and hold times are all clearly defined.

BOX 6
Reliability of testing between the designated laboratories

To assess the consistency between the designated laboratories, two products were tested at both KWR and NSF. Each laboratory independently developed product-specific testing protocols for the two products. At both laboratories three sampling units each of the two products were tested, with influent concentrations for all organisms sufficient to meet 3-star performance targets. The results from the laboratories were consistent for both products: one product met the 2-star target, limited by its virus performance, while the other product fully met the 3-star performance targets for all three pathogen classes. Given viruses are the most difficult class of pathogen to manipulate, the consistency between labs for this class of organism in particular, demonstrates quality measures are being met.

Designated testing laboratories

The WHO designated laboratories, KWR and NSF, were selected based on expertise, capabilities and independence. These laboratories are accredited to ISO 17025, demonstrating their competence in testing and calibration and providing quality assurance that includes both management and technical requirements:

- Management requirements relate to the operation and effectiveness of the quality management system within the laboratory, including defined responsibilities and tasks of staff, procedures for ensuring the quality of test results and clear document control/ reporting procedures.

- Technical requirements include factors which determine the correctness and reliability of the tests and calibrations performed in laboratory (Box 6). These include staff competence, environment control, testing methodology, equipment and measurement traceability, and reporting of test and calibration results.

In addition to demonstrated technical capability, KWR and NSF are independent of industry and the head of each institution and the staff responsible for the testing activities are required to disclose potential conflicts of interest. The institutions also have adequate mechanisms in place to address and manage potential conflicts and safeguards to ensure the integrity of testing and the results.

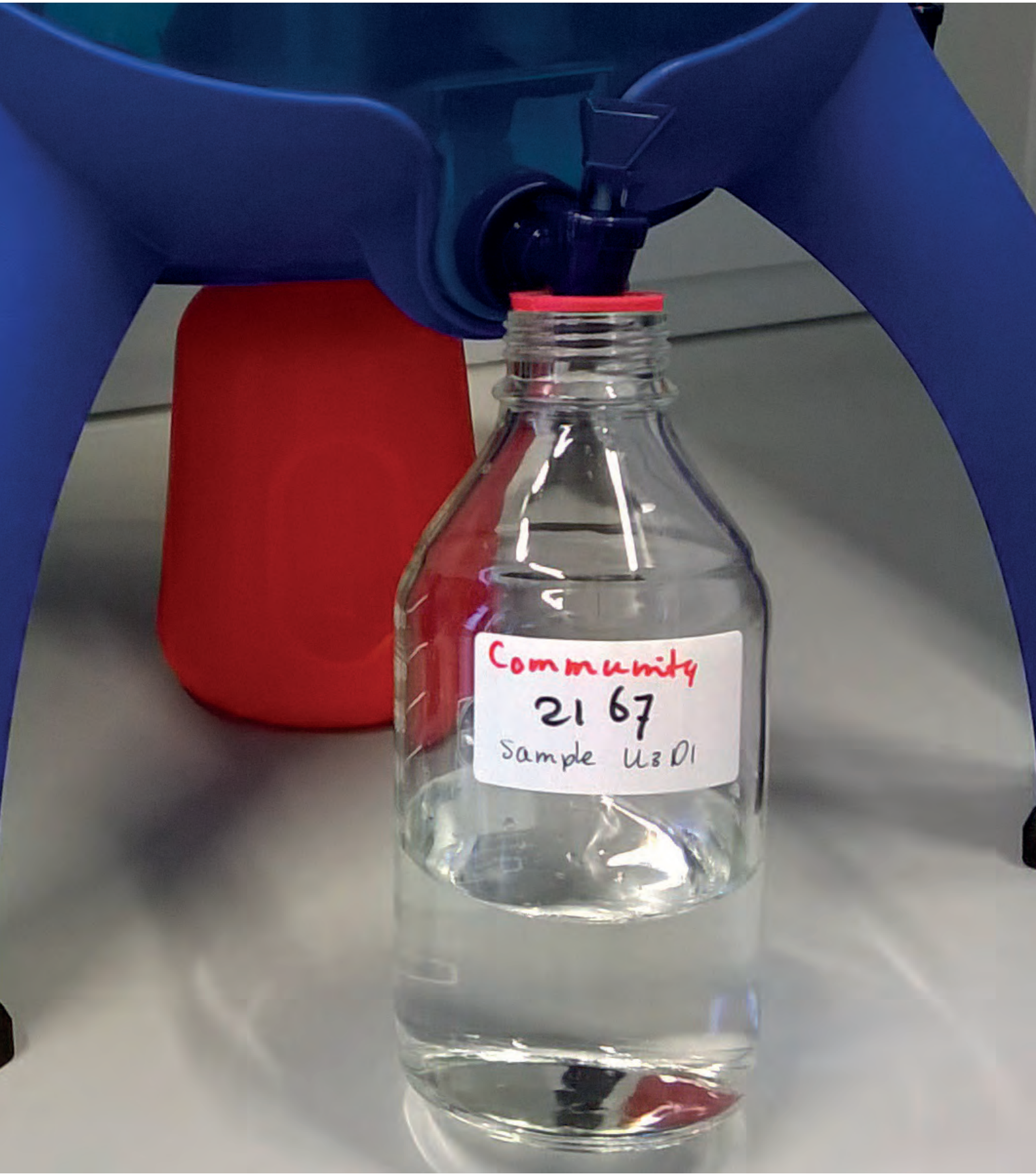
Laboratory learning exchanges

Communication between designated testing facilities also helps to ensure consistent evaluation. KWR and NSF, both WHO Collaborating Centres, have met and maintain regular communication to produce a common understanding of all the evaluations and subsequent reporting and conduct testing on a not-for profit basis as part of Collaborating Centre activities.

1.1.4 Overview of the product testing

For each of the products that undergo laboratory testing, manufacturers are required to provide three production units for devices, and sufficient samples for triplicate replicates in three production lots for chemical disinfectants.[1] Each of the products is tested against the protocols specific to the technology class that they represent. Further information on these technology-specific protocols can be found in Annex 1. The actual setup employed during testing follows the manufacturer's instructions for use, including doses to be applied, contact times, requirements for pre-conditioning, etc. Supporting information submitted by manufacturers describing their product and its operation and maintenance is also reviewed.

1 Each unit from the three lots is required to meet or exceed the performance requirements set out in Table 2. However, a maximum deviation of 10% in the sample points is allowed, provided that the variance is not greater than 1 $\log_{10}$.


Community
21 67
Sample U3 D1

1.2 HWT products evaluated in Round I

In 2014, WHO issued the first call to HWT manufacturers to submit EOIs. A total of 29 EOIs were received from 26 manufacturers. After the initial screening, 12 products did not meet the eligibility criteria and thus did not proceed to the full evaluation. Details of the screening criteria and EOI reviews are provided in Annex 1. Some manufacturers withdrew from the evaluation for various reasons, including uncertainty about the readiness of their product for testing and concerns about the testing costs.[1] In total, ten products from eight manufacturers proceeded to evaluation under the Scheme (Table 3).

Of the ten products that were evaluated, six underwent full laboratory testing and four underwent abbreviated evaluations. These products represent filtration, solar, UV, chemical and combination technologies. A brief description of these products and the technology class they represent is provided in the following sections.

TABLE 3
Products evaluated in Round I of the Scheme

Technology	Product	Manufacturer	Evaluation procedure
Membrane ultrafiltration	LifeStraw Family 1.0	LifeStraw SA	Abbreviated procedure: Desk review of existing data
Membrane ultrafiltration	LifeStraw Family 2.0		Full laboratory testing
Membrane ultrafiltration	LifeStraw Community		Full laboratory testing
Ceramic filtration	TEMBO Filter Pot	Upendo Women's Group MSABI	Full laboratory testing
Flocculation-disinfection	P&G Purifier of Water	The Procter & Gamble Company	Abbreviated procedure: Desk review of existing data
UV disinfection	Waterlogic Hybrid / Edge Purifier	Qingdao Waterlogic Manufacturing Company	Full laboratory testing
Solar disinfection	WADI	Helioz GmbH	Full laboratory testing
Chemical disinfection	H2gO Purifier	Aqua Research LLC	Abbreviated procedure: Desk review of existing data
Chemical disinfection	Aquatabs	Medentech Limited	Abbreviated laboratory testing and desk review of existing data
Chemical disinfection	Silverdyne	World Health Alliance International Inc.	Full laboratory testing

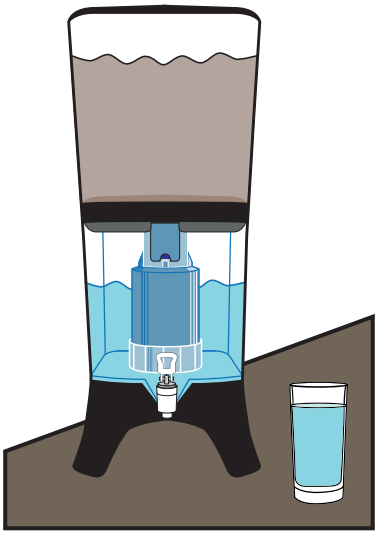
1 The full cost of evaluation depends on the technology and evaluation protocol to be followed. Subject to the availability of funds, WHO may, at its sole discretion, decide to waive part of the cost for applicants, and in Round II, more funds will be made available for this purpose.

MEMBRANE FILTRATION (ULTRAFILTRATION)

In general, filters reduce microbial contaminants from drinking-water by a combination of physical and chemical processes, including size exclusion and adsorption. A key determinant of their performance is the pore size of the filter, and not all membrane types are effective against small microorganisms such as viruses. A brief overview of the microbial performance, limitations and advantages of ultrafiltration membranes (and not membranes in general) is provided below.

Microbial performance	• Effective against viruses (depending on the integrity of the membrane), bacteria and protozoa
Advantages	• Visual improvement in treated water
Limitations	• Regular cleaning of filters required • Requires reliable supply chain for spare parts • Does not provide residual protection against recontamination unless treated water is safely stored • Membrane fouling
Application	• Most appropriate in areas where: • There is external funding or microfinance schemes to support the initial cost of the filter • There is a distribution network for replacement of broken parts • User training on how to correctly maintain and use the filter is feasible

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009



LIFESTRAW FAMILY 1.0, LIFESTRAW FAMILY 2.0 AND LIFESTRAW COMMUNITY

Countries of manufacture

The filter membranes and cartridge are manufactured in Korea. The plastic moulding for LifeStraw Family 2.0 and LifeStraw Community is manufactured in China.

Treatment technology

Membrane ultrafiltration

Product description

The LifeStraw filters are available in three versions, namely LifeStraw Family 1.0, 2.0 and Community. During filtration, microorganisms such as bacteria, viruses and protozoa are physically removed from water as it is forced through hollow fibre membranes under gravitational pressure.

The LifeStraw Family 1.0 comprises a 2 L reservoir containing a pre-filter to remove coarse particles, which is attached to a hose that connects to the ultrafiltration hollow fibre membrane[1] cartridge and a tap. When the tap is turned on, water in the reservoir travels down the hose and is forced through the filter cartridge and released through the tap. The filter does not come with a safe storage container, and has to be hung or suspended above the storage container to be filled. The estimated flow rate of the filter when new is 12 L/hour.

The LifeStraw Family 2.0 and LifeStraw Community are based on the same ultrafiltration membrane technology as the LifeStraw Family 1.0. The 2.0 is a table top version of the LifeStraw range, and comprises a 6.0 L raw water tank and a built-in 5.5 L safe storage water tank with a tap. The estimated flow rate of the filter when new is at least 2.5 L/hour. The LifeStraw Community is a high-volume version designed for use in community and institutional settings. It has a total fill capacity of 50 L, with raw water and safe storage tanks of 25 L each. The estimated flow rate of the filter when new is at least 12 L/hour. The full product descriptions and use instructions can be found at the product webpage: http://www.vestergaard.com/our-products/lifestraw

Product specifications

Version	Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
LifeStraw Family 1.0	None	Daily backwash and pre-filter cleaning is recommended Reusable: estimated lifespan of up to 5 years	Can be hung on a wall; Does not include a safe storage container	1,000,000
LifeStraw Family 2.0			Table top; Includes a safe storage container	150,000
LifeStraw Community			Table top or free-standing Includes a safe storage container	15,000

[a] Based on information provided by the manufacturer

Product evaluation

The evaluation of the LifeStraw filters consisted of a desk review of existing data of the Family 1.0 and laboratory testing of the Family 2.0 and Community versions. Testing followed requirements of the technology-specific protocol for gravity-fed membrane filters. Following the manufacturer's use instructions, three lots of the products, run in triplicate, were evaluated to determine their reduction performance against bacteria and viruses. Testing against *Cryptosporidium parvum* was not required, as filtration devices with a pore size of less than 1 micron would be capable of removing oocysts (size ranging between 2 to 50 microns), and if the membrane was compromised, the presence of smaller viruses or bacteria in the treated water would clearly demonstrate a fault in the filter.

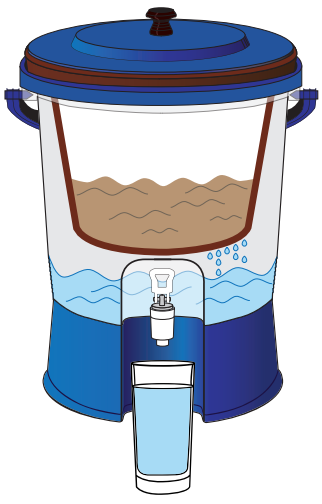
1 The hollow fibre membrane can filter particles down to 0.02 microns.

POROUS CERAMIC FILTRATION

Ceramic filtration relies on the physical removal of contaminants from water by a combination of size exclusion and adsorption. The most common ceramic filter shapes are pots and candles, although discs are also available. The filters may also be enhanced by impregnating or coating with a bacteriostatic agent such as silver nitrate solution or colloidal suspensions of silver. A brief overview of the microbial performance, limitations and advantages of porous ceramic filters is provided below.

Microbial performance	• Effective against bacteria and protozoa • Limited effectiveness against viruses
Advantages	• Simple to use • Visual improvement in treated water • One-time capital cost • Possibility of local production benefits economy
Limitations	• Lack of residual protection presents potential for recontamination if no attached safe storage container is provided • Variability in quality of locally produced filters • Filter breakage requires reliable supply chain • Need to regularly clean filters and receptacles • Low flow rate of 1–3 litres per hour (slower in turbid waters)
Application	Most appropriate in areas where: • There is capacity for quality ceramic filter production / quality management processes in place • There is a distribution network for replacement of broken parts • There is external funding or microfinance schemes to support the initial cost of the filter • Educational messages can reach the target population to encourage correct and consistent use

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009



TEMBO FILTER POT

Country of manufacture

Tanzania

Treatment technology

Ceramic pot filter

Product description

The TEMBO Filter Pot is made from a mix of clay and rice husk, which is pressed in a mould and fired in a kiln that reaches temperatures of 700°C. A layer of a colloidal silver solution is painted over the internal surface of the filter. The filter is sold as a separate unit, or set in a 20 or 30 L plastic bucket equipped with a spigot. Water poured into the ceramic pot filters through the pores under gravity and is collected in the plastic bucket. According to the manufacturer, the flow rate ranges between 1 and 5 L per hour. The full product description, illustrations and use instructions can be found on the manufacturer's webpage: www.msabi.org

Product specifications

Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
None	Once a year the pot should be cleaned inside with water, soap and a brush (provided to the consumer) to remove build-up of solids; Reusable: estimated lifespan of 2-3 years	Table top	2,000

[a] Based on information provided by the manufacturer

Product evaluation

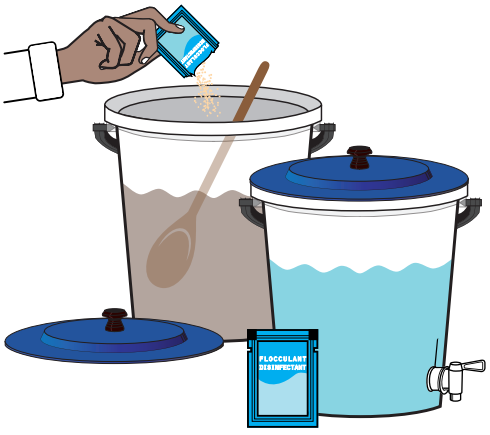
The evaluation of the TEMBO Filter Pot consisted of laboratory testing to provide independent data on the product's microbiological performance. Testing followed requirements of the technology-specific protocol for ceramic pot filters. Following the manufacturer's use instructions, including conditioning, three units (triplicate replicates) were tested for all three classes of pathogens in general and challenge test waters. Testing was stopped prior to full test capacity due to very low flow of the test waters in the pots. According to the information provided by the manufacturer, the average flow rate for the TEMBO Filter Pots is 1-5 L/hour. However, during testing it took more than 24 hours to filter an 8 L of sample water, indicating a flow rate of less than 0.5 L/hour.

FLOCCULATION-DISINFECTION

Flocculant-disinfectants employ a multi-barrier approach to water treatment. The flocculant encourages suspended and larger microorganisms such as protozoa to bind to each other and settle to the bottom of the water container, while the disinfectant inactivates the smaller microorganisms such as bacteria and viruses. A brief overview of the microbial performance, limitations and advantages of flocculant-disinfectants is provided below.

Microbial performance	• Effective against viruses, bacteria and protozoa
Advantages	• Residual protection against recontamination • Reduction of some heavy metals (e.g. arsenic) and particle-associated pesticides • Visual improvement in treated water • Typically available in small sachets which are easily transported • Non-hazardous classification, long shelf-life
Limitations	• Need for multiple steps to use the product, requires additional user support • Requires reliable supply chain • High relative cost per litre treated • Potential user taste and odour objections
Application	Most appropriate in areas where: • Water is of relatively high turbidity • There is a consistent supply chain • Educational messages can reach the target population to encourage correct and consistent use

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009



P&G PURIFIER OF WATER

Country of manufacture

Singapore

Treatment technology

Flocculant-disinfectant

Product description

The P&G Purifier of Water is a sachet containing powdered ferric sulfate and calcium hypochlorite. The ferric sulfate acts as a coagulant which aggregates suspended particulates and microorganisms in water. The coagulation results in the creation of larger floccules that then settle in the base of the water vessel. The calcium hypochlorite acts as a disinfectant. It is available in 4 gram sachets that can each treat 10 L of water. The full product description, illustrations and use instructions can be found on the product webpage: www.pghsi.com/pghsi/safewater/development.shtml

Product specifications

Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
None	No maintenance required. Consumable: estimated shelf-life of 3 years	Available as single use sachets	130,000,000

[a] Based on information provided by the manufacturer

Product evaluation

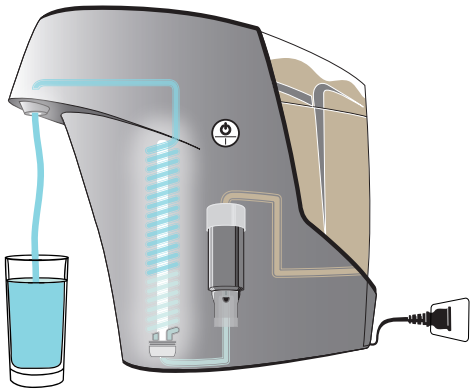
Given the extensive evidence base on flocculants-disinfectants in general and the previously conducted rigorous testing, the evaluation of P&G Purifier of Water consisted only of a desk review of existing data on performance against viruses, bacteria and protozoa. Supporting information submitted by the Procter & Gamble Company describing the product and its use was also reviewed.

UV DISINFECTION

UV radiation inactivates microbial organisms by altering their nucleic acids and proteins, which impairs their cell binding and/or ability to be replicate. A brief overview of the microbial performance, limitations and advantages of UV technologies is provided below.

Microbial performance	• Effective against viruses, bacteria and protozoa
Advantages	• Simple to use • Minimal change in taste of the water
Limitations	• Need for pre-treatment (filtration or flocculation) of waters of higher turbidity • Does not provide residual protection against recontamination unless treated water is safely stored • Requires a power source and clean UV lamp to operate effectively • Requires reliable supply chain and professional maintenance • High relative cost per litre treated
Application	Most appropriate in areas where: • Electricity or other power source is available

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009



WATERLOGIC HYBRID / WATERLOGIC EDGE PURIFIER

Country of manufacture

China

Treatment technology

UV disinfection with pre-filtration

Product description

The Waterlogic Hybrid / Edge Purifier is an electric water treatment device fitted with a carbon pre-filter and UV lamp. The device has a detachable 1.5 L reservoir that holds the raw water. Water passes the pre-filter and UV lamp and is dispensed through a spout. The filter does not include an attached safe storage container. The full product description, illustrations and use instructions can be found on the manufacturer's webpage: www.waterlogic.com

Product specifications

Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
Continuous electric power supply	UV lamp and carbon filter require replacement every 6-12 months, depending on local water quality. Reusable: estimated lifespan of 5 years	Counter top	15,000

[a] Based on information provided by the manufacturer

Product evaluation

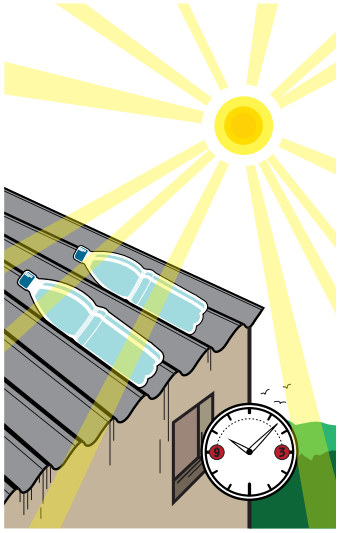
The evaluation of the Waterlogic Hybrid / Edge Water Purifier consisted of laboratory testing of the product's performance against all three classes of pathogens. Testing followed requirements of the technology-specific protocol for UV disinfectants. Following the manufacturer's use instructions, three units (triplicate replicates) were evaluated in general and challenge test waters. The testing was concluded on Test Day 8, prior to full sample collection, due to reduced flow. The product's performance was evaluated based on the data collected.

SOLAR DISINFECTION

Solar disinfection inactivates microbial organisms through a combination of UV radiation, oxidative activity associated with dissolved oxygen products and heat. Transparent containers are filled with water and exposed to sunlight. In general, polyethylene terephthalate (PET) bottles are considered most practical and ideal for solar disinfection. A brief overview of the microbial performance, limitations and advantages of solar technologies is provided below.

Microbial performance	• Potentially effective against viruses, bacteria, and protozoa depending on the container material and climatic and weather conditions
Advantages	• Simple to use • No cost to the user after obtaining the PET bottles • Minimal change in taste of the water • Minimal likelihood of recontamination when held in disinfecting container
Limitations	• Need for pre-treatment (filtration or flocculation) of waters of higher turbidity • Volume to treat dependent on availability of clean, intact PET bottles • Lack of visual improvement in water aesthetics to reinforce benefits of treatment • Relatively long time to treat water and variability depending on sun intensity • Effectiveness of treatment depends on the specific water matrix and temperature reached
Application	Most appropriate in areas where: • Bottles for treatment are available • Educational messages can reach the target population to encourage correct and consistent use

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009



WADI

Country of manufacture

Austria

Treatment technology

UV measurement device

Product description

WADI is a solar powered UV measurement device that is used to indicate sufficient treatment via solar disinfection. According to the information provided by the manufacturer, it can be placed next to an unlimited number of PET plastic bottles (maximum single bottle volume of 3 L) and shows a happy smiley face when sufficient UV radiation has made the water in the PET plastic bottles safe to drink. The full product description, illustrations and use instructions can be found on the manufacturer's webpage: www.helioz.org

Product specifications

Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
Solar power	No maintenance required. Reusable: estimated lifespan of 3 years	Handheld	5,000

[a] Based on information provided by the manufacturer

Product evaluation

The evaluation of the WADI consisted of laboratory testing of the product's performance against all three classes of pathogens. Testing followed requirements of the solar (UV and heat) technology-specific protocol. Following the manufacturer's use instructions, three units (triplicate replicates) were evaluated for all three classes of pathogens in general and challenge test waters. A solar lamp was used to provide 550W/m^2 of simulated outdoor solar radiation in a laboratory setting. This irradiance corresponds to what would likely be observed between latitude 15°N and 35°N as well as 15°S and 35°S, where the majority of developing countries are located.

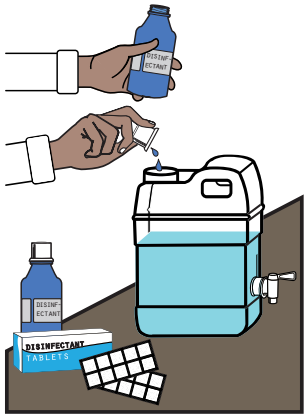
CHEMICAL DISINFECTION (CHLORINATION)

Chemical disinfectants primarily act against microorganisms by chemically altering (often oxidizing) their biochemical building blocks and disrupting surface attachment molecules and vital cell functions. The most common disinfectants are chlorine based, although iodine based or metallic disinfectants such as ionized copper and/or silver are available. A brief overview of the microbial performance, limitations and advantages of chlorination is provided below.

Microbial performance	• Effective against bacteria and some viruses • Ineffective against protozoan cysts such as *Cryptosporidium parvum*[1]
Advantages	• Residual protection against recontamination • Simple to use • Possibility of local production may benefit economy • Low cost
Limitations	• Less effective in turbid or organic-rich waters[2] • Potential user taste and odour objections • Requires reliable supply chain • Necessity of ensuring quality control of product
Application	Chlorination products are widely used in emergencies, due to their ease of use and transport, and affordability, among other factors. It should be noted that chlorination products are most appropriate in areas where: • The pathogen of concern is known (e.g. *Vibrio cholerae*), as chlorine does not provide protection against some protozoa • There is a consistent supply chain or there are quality management procedures in place for onsite production • Water is of relatively low turbidity and colour • Educational messages can reach the target population to encourage correct and consistent use

Adapted from: WHO/UNICEF, 2012a and Lantagne and Clasen, 2009

The chemical disinfectants evaluated in Round I and the evaluation procedure followed are outlined in the sections that follow.



1 Because of this limitation, products based on simple chlorination alone are unlikely to achieve a performance target higher than 1-star (★).

2 High levels of dissolved organic carbon in water can react with chlorine to form potentially hazardous by-products. However, the health risks from these by-products at the levels at which they occur in drinking-water are relatively small in comparison with the risks associated with inadequate disinfection. As such, disinfection should not be compromised in attempting to control such by-products (WHO, 2011b).

H2gO PURIFIER

Country of manufacture

China

Treatment technology

Electrolytic chlorine generator

Product description

The H2gO Purifier is a handheld device that produces a mix of sodium hypochlorite and hydrogen peroxide solution from salt and water through an electrolytic process. The resulting disinfectant solution is then added to the water to be treated. The H2gO Purifier produces sufficient disinfectant to treat water volumes of 1, 2, 5, 10, or 20 L. The full product description, illustrations and use instructions can be found on the manufacturer's webpage: www.h2gopurifier.com

Product specifications

Power requirements	Maintenance and lifespan	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
Energy source (either the sun or power supplied via USB) required for battery recharge	No maintenance required. Reusable: estimated lifespan of 10 years	Handheld	3,000

[a] Based on information provided by the manufacturer

Product evaluation

The evaluation of H2gO Purifier consisted of a desk review of existing data on its performance against bacteria and viruses only. The submitted data on performance against viruses and bacteria were reviewed as an abbreviated procedure against the technology-specific protocol for chlorine disinfectants. In general, the existing evidence suggests that disinfection by chlorine alone or mixed oxidants is ineffective against *Cryptosporidium* oocysts at concentrations that would be within taste and odour thresholds and contact times reasonably reflective of field use. Although some experimental data were submitted on the product's performance against protozoan cysts including *Cryptosporidium* oocysts, they were based on high doses and long contact times (up to four hours). These data were therefore not considered in the review as in practice the recommended contact time is 30 min and achieving longer times would require considerable user education.

AQUATABS

Country of manufacture

Ireland

Treatment technology

Chlorine disinfectant

Product description

Aquatabs are effervescent chlorine tablets with sodium dichloroisocyanurate (NaDCC) as the active ingredient (NaDCC is also known as sodium dichloro-s-triazinetrione or sodium triclosene). The tablets are available as foil-wrapped strips of various strengths, according to the volume (1 to 20 L) and nature of water to be treated. The full product description, illustrations and use instructions can be found on the manufacturer's webpage: www.medentech.com

Product specifications

Power requirements	Maintenance and shelf-life	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
Energy source (either the sun or power supplied via USB) required for battery recharge	No maintenance required; Consumable: estimated shelf-life of 3 years	Available as single use tablets	750,000,000

[a] Based on information provided by the manufacturer

Product evaluation

The evaluation of Aquatabs consisted of abbreviated laboratory testing to determine their performance against protozoa, and a desk review of existing data on their performance against viruses and bacteria. Testing followed requirements of the technology-specific protocol for chlorine disinfectants. Following the manufacturer's use instructions, three lots of the product, run in triplicate, were evaluated to determine their inactivation performance against *Cryptosporidium* oocysts. The product disinfectant residual as free available chlorine in the finished water was also measured.

SILVERDYNE

Country of manufacture

United States of America (USA)

Treatment technology

Colloidal silver disinfectant

Product description

Silverdyne is a liquid colloidal silver suspension that is available in 30 and 60 mL bottles. According to the information provided by the manufacturer, each 30 mL bottle treats approximately 1,200 L of water. The full product description, illustrations and use instructions can be found on the product webpage: http://www.whaintl.com/index.php/silverdyne

Product specifications

Power requirements	Maintenance and shelf-life	Other features	Estimated number of units distributed/ procured in 2013/2014[a]
None	No maintenance required; Consumable: estimated shelf-life of 3 years	Available as small bottles	300,000

[a] Based on information provided by the manufacturer

Product evaluation

The evaluation of Silverdyne consisted of laboratory testing to determine the product's performance against viruses and bacteria. In general, the evidence suggests silver is not effective against *Cryptosporidium*. Therefore, the product's performance against this pathogen class was not evaluated. Testing followed requirements of the technology-specific protocol for silver disinfectants. Following the manufacturer's use instructions, three lots of the product, run in triplicate, were evaluated to determine their inactivation performance against bacteria and viruses in general and challenge test waters. The product disinfectant residual in the finished water was also measured.

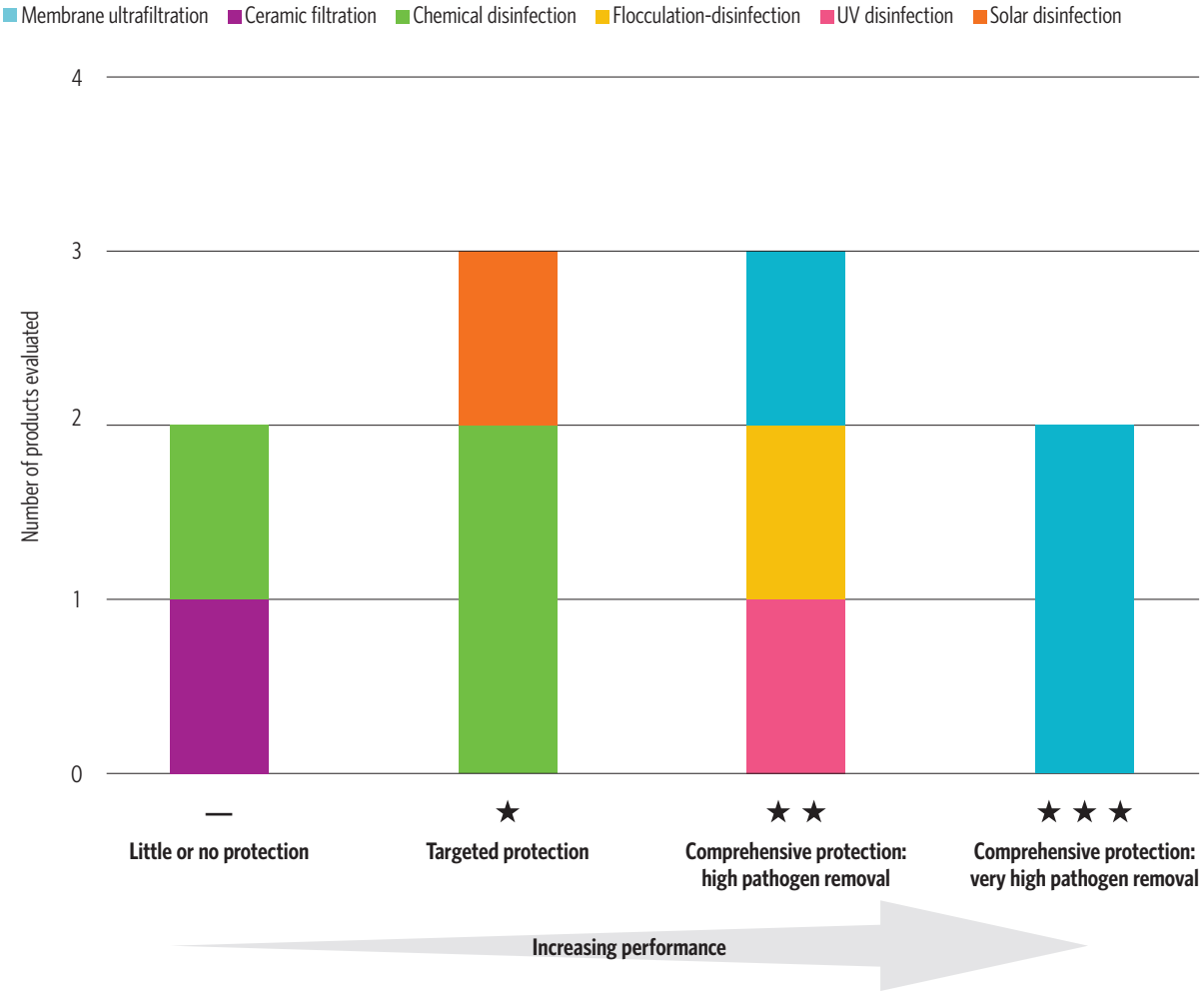
1.3 Results

The results are summarized in two sub-sections, based on the performance evaluation and review of product information.

1.3.1 Microbiological performance of HWT products

Products classified as providing comprehensive protection with very high removal (★★★) are those that demonstrate at least 4 $\log_{10}$ reduction against bacteria and protozoa, and at least 5 $\log_{10}$ reduction against viruses. Products classified as providing comprehensive protection with high removal (★★) are those that demonstrate at least 2 $\log_{10}$ reduction against bacteria and protozoa, and at least 3 $\log_{10}$ reduction against viruses. As shown in Figure 4, there is some variability in performance and some of the products evaluated do not meet any of the performance targets.

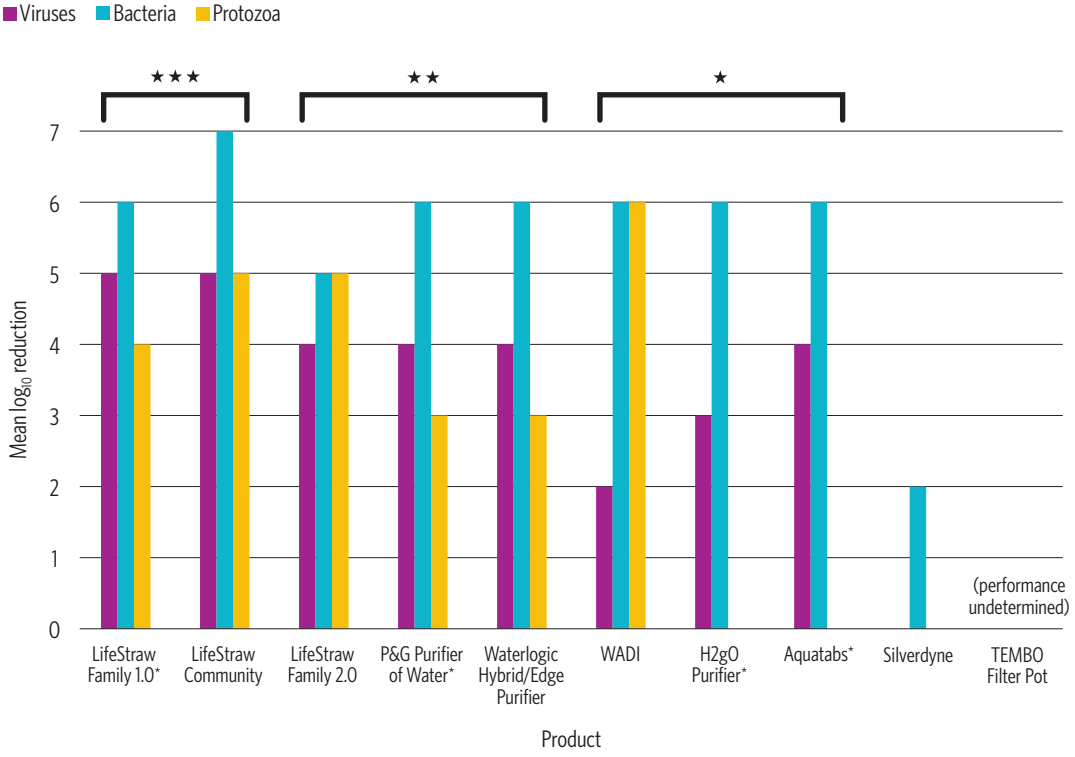
FIGURE 4
Performance classification of HWT technologies evaluated in Round I



Of the six classes of technologies evaluated, three were found to meet performance targets for either 3-star or 2-star classification. These technologies are membrane ultrafiltration devices, a flocculant-disinfectant and a UV disinfection device. The mean log reductions for each of the evaluated products are presented in Figure 5.

FIGURE 5

Log_{10} reduction of bacteria, viruses and protozoa met or exceeded by products evaluated in Round I



Notes:
Evaluation based on existing data; test organisms may differ from those used under the Scheme
LifeStraw Family 2.0 and *LifeStraw Community*: Performance against protozoan cysts based on existing data
LifeStraw Family 2.0: Overall the *mean* log reductions demonstrated meet performance targets for 3-star (★★★), but the performance target for viruses was not *consistently* met across all samples, and therefore product was classified as 2-star (★★)
WADI: Overall the *mean* log reductions demonstrated meet performance targets for 2-star (★★), but the performance target for viruses was not *consistently* met across all samples, and therefore product was classified as 1-star (★)
H2gO Purifier: Performance against protozoan cysts was not evaluated due to the previously mentioned limitations of chlorination
Aquatabs: Abbreviated evaluation against protozoan cysts demonstrated no reduction
Silverdyne: Evaluation against viruses demonstrated no log reduction, and no evaluation against protozoan cysts was conducted due to limited evidence of effectiveness
TEMBO Filter Pot: Performance was undetermined due to low flow in the filter

The results of the evaluation reveal the following key findings:

Half of the ten products evaluated were found to provide comprehensive protection against all three pathogen classes. These are: the three membrane ultra-filters, the flocculant-disinfectant, and the UV disinfectant. These products were found to meet the performance targets for either 3-star (★★★) or 2-star (★★), and are classified as providing *Comprehensive protection*, with very high or high removal of three classes of pathogens, respectively.

Three of the products evaluated were found to provide targeted protection against two of three classes of pathogens. These are the chlorine tablets, the electrolytic chlorine generator and the solar disinfection indicator. The chlorination products were found to be effective against and bacteria and viruses only – achieving at least 6- and 3-log_{10} respectively – but were found not to be effective against *Cryptosporidium* oocysts. Therefore, these chlorination products meet the performance targets for 1-star (★), and are classified as providing *Targeted*

1 This refers only to the treatment technologies represented by the products evaluated under the Scheme and found to meet the performance targets, and not all such technologies.

protection against bacteria and viruses only. The solar disinfection device was found to be effective against bacteria and protozoa, and also demonstrated reasonable performance against viruses. However, it did not *consistently* meet the performance target for viruses across all samples and is therefore classified as providing *Targeted protection* against bacteria and protozoa only.

Not all products were found to be effective in reducing pathogens from drinking-water. Two of the products evaluated were found to not meet the minimum performance targets (1-star). This underscores the importance of rigorous, consistent and independent evaluation of HWT products, as distribution of underperforming products will not result in expected health gains, regardless of consistency and correctness of use.

Other selected findings include:

Product performance may vary significantly between production units. Two of the products evaluated (a membrane ultrafiltration device and a solar disinfection indicator) did not consistently meet the required performance targets across all samples. For these products, the mean $\log_{10}$ reduction for the viral surrogates MS2 and/ or phiX174 varied by more than 1 $\log_{10}$ across the samples. Therefore, although the *mean* $\log_{10}$ reductions against the viral surrogates of these devices met or exceeded the performance targets, more than 10 % of the samples did not meet the target log reductions and therefore the performance targets were not fully met. Such variation in performance among product units highlights the importance of performing replicate analyses and testing multiple lots to evaluate the consistency in manufacture. Variation in performance among units may suggest variability in production highlighting a need to identify gaps in quality product manufacturing, especially for filters where there are several parts which must be fit together. It is worth noting that although the membrane ultrafiltration device did not consistently meet the 5 $\log_{10}$ reduction for viruses, the average removal was higher than 5 log and the performance of membrane filters has been shown to progressively improve over time, with increased clogging of the filter pores (Madsen et al., 2010).

Special consideration may need to be given to quality management of local products. It was not possible to classify the performance of the ceramic pot filter, due to the very low flow rate that was observed during testing. Thus, without being able to filter water, testing was concluded prematurely and the performance was undetermined. This suggests poor quality control in manufacturing, as locally manufactured products have been shown to be especially susceptible to inconsistencies in performance (the Ceramics Manufacturing Working Group, 2011).

1.3.2 Findings from the reviews of product information and existing data

In addition to the laboratory testing, supporting information for each product was reviewed, including the product labels, instructions for use and existing performance-related information. Selected findings from this review are:

Manufacturer testing, in some cases, is insufficient to support claims as testing does not cover all three classes of pathogens, and is largely limited to faecal coliforms and physico-chemical parameters. Communication and facilitating the understanding of the need to demonstrate comprehensive evaluation results to decision-makers who are responsible for procuring HWT products (such as national governments, donors and non-governmental organizations) is vital in order to identify limitations in various technologies and decipher claims about product performance.

Existing testing is often conducted under ideal conditions that are not reasonably reflective of actual use in the field. In particular, the existing evidence suggests that chemical disinfectants alone are ineffective against protozoan oocysts such as *Cryptosporidium* at concentrations that would be within taste and odour thresholds, and at contact times that would be reasonably reflective of field use. Among the existing performance data reviewed, two disinfection products demonstrated at least 2 $\log_{10}$ reduction against *Cryptosporidium* oocysts, but used doses 2 to 4 times higher than that recommended on the product label and contact times ranging from 2 to 4 hours.

Unclear product labelling and use instructions. Consistent with the findings of Murray et al. (2014), unclear use instructions and product labelling were observed in two products. This may lead to confusion, possible misuse and underperformance of products.

1.3.3 Interpretation of evaluation results

Products that meet 3-star (★★★) or 2-star (★★) performance targets are classified as providing *Comprehensive protection* against the three main classes of pathogens which cause diarrhoeal disease in humans. The use of these products is encouraged where there is no information on the specific pathogens in drinking-water or where piped supplies exist but are not safely managed.

Products that meet that meet the performance targets for at least 2-star (★★) for only *two* of the three classes of pathogen are given one star (★) and are classified as providing *Targeted protection*. In general, the use of these products may be appropriate in targeted situations where the burden of diarrhoeal disease is high due to known classes of pathogens. For instance, although chlorination is ineffective against protozoa, it is known to be effective against bacteria and viruses. Thus, in a situation where the causative agent of disease is known, such as *Vibrio cholerae*, chlorination can play an important role in improving the quality of water, and is widely used in cholera outbreaks and other emergencies (Box 7). Given that cholera outbreaks are still frequent in many countries and that there were an estimated 190,500 cases and 2,200 deaths in 2014 (WHO, 2015b), chlorine will continue to serve an important role in such situations.

BOX 7
Household water treatment in emergencies

Safe drinking-water is an immediate priority in most emergencies, and HWT can be an effective emergency response intervention. Common water treatment options in emergencies include chlorine tablets and solutions, boiling promotion and safe storage. However, a number of key elements should be considered when implementing HWT in emergencies. These include having a selection of HWT options available, user training and materials necessary to use the treatment options, obtaining local registration of HWT products and user knowledge and acceptability of chlorine dosage.

Lantagne and Clasen (2009)

1.3.4 Use of results in selecting HWT products

The results of the evaluation are intended to assist procurers in making informed purchases of these products. It must be noted that the evaluation results presented in this report represent an initial step in decision-making.

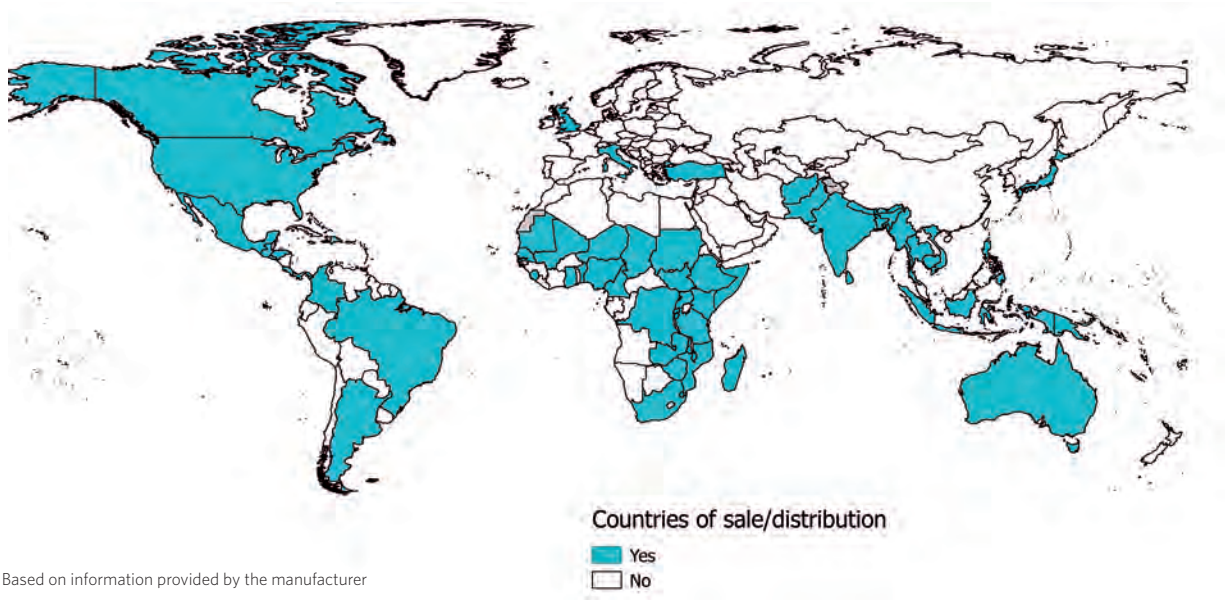
In addition to microbiological performance, supply chains, cost, user preferences as well as user compliance (correct and consistent use) are extremely important (Box 8). Regardless of the star rating, products need to be used correctly and consistently in order to achieve health gains. Evidence suggests that products need to be used at least 90 % of the time in order to achieve health gains from HWT (Brown and Clasen, 2012). A slightly lower performing (e.g. 2-star) product that is used at least 90 % of the time to treat faecally-contaminated water can provide several times more protection than a higher performing (e.g. 3-star) product that is used less consistently (Brown and Clasen, 2012). Thus, given a choice between a product whose performance is classified as 3-star versus one whose performance is classified as 2-star, the existing evidence points to the product with the higher user compliance as the better choice.

BOX 8
Selecting HWT products

There is no single HWT product that is appropriate for all contexts. However, microbiological performance should be the first consideration in product selection, followed by local contextual factors that influence correct and consistent use. These factors include availability, cost, user preferences and behaviour. WHO is working with partners to develop specific resources and tools to further guide product selection in this regard.

1.4 Global distribution of products evaluated

FIGURE 6
Global reach of the HWT products evaluated in Round I[a]



[a] Based on information provided by the manufacturer

PRODUCTS EVALUATED IN ROUND I OF THE SCHEME HAVE A GLOBAL REACH, SPANNING CLOSE TO

60 COUNTRIES

(Figure 6)

CONSUMABLE DISINFECTANT PRODUCTS EVALUATED IN ROUND I OF THE SCHEME TRANSLATE TO CLOSE TO

900 MILLION

individual tablets, sachets and bottles distributed/ procured in 2013/2014.

DURABLE PRODUCTS INCLUDING FILTERS, UV AND SOLAR TECHNOLOGIES TRANSLATE TO CLOSE TO

1.7 MILLION

individual tablets, sachets units distributed/ procured in 2013/2014.


60 ml
FOR WATER DISINFECTION

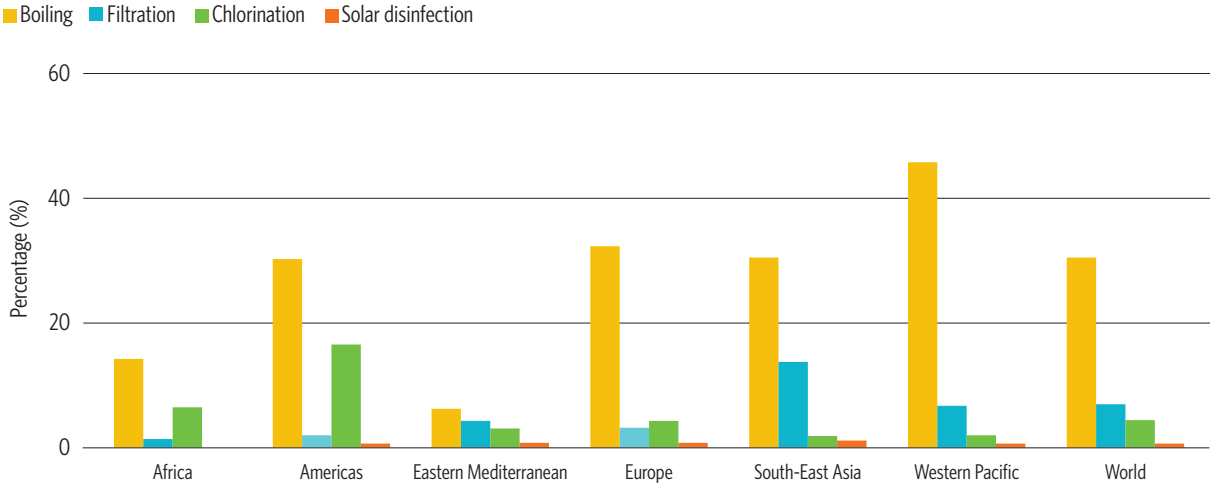
2. Implications: supporting availability and scaling up of quality HWT and safe storage

Globally, an estimated 1.1 billion people (30 % of households) in low- and middle-income countries report using household water treatment (HWT) and safe storage (WHO, 2014a). As Figure 7 shows, the practice is particularly common in the regions of the Western Pacific and South-East Asia.

Boiling is the most commonly used method. Figure 7 also highlights that filtration is fairly common in the South-East Asian and Western Pacific regions, while chlorination is more common in the regions of the Americas and Africa (WHO, 2014a).

A number of complimentary areas of work are necessary to ensure that quality HWT products are available and used by populations with unsafe drinking-water. The following section presents the findings of a rapid market assessment to understand use of HWT in key countries, including growth of particular technologies and national regulatory structures. This is followed by a discussion of key scaling up efforts to better monitor, target and understand the use of quality HWT.

FIGURE 7
Percentage of the population reporting HWT, by WHO region (WHO, 2014a)



2.1 Rapid market assessment

In early 2015, WHO commissioned a rapid market assessment to identify HWT products that are currently on the market and could potentially be evaluated in Round II of the Scheme, and investigate the regulatory environment surrounding these products. Due to resource constraints, the market assessment was limited to the WHO regions of Africa, South-East Asia and the Western Pacific. The market assessment was based on a literature review and interviews with manufacturers of HWT products, implementing agencies (including non-governmental organizations) and national regulatory officials. In addition, field visits took place in three countries where there was an expressed need and capacity to strengthen HWT regulation and evaluation (Ethiopia, Ghana and Viet Nam).

2.1.1 Sub-Saharan Africa: Estimated use and regulation of HWT

The findings indicate that there is wide variation in HWT use among countries in the African region, ranging from 4 % in the Democratic Republic of Congo to 49 % of the population in Rwanda (Annex 2). Consistent with previous reports on HWT use (Rosa & Clasen 2010; WHO, 2014a), apart from boiling, chlorination remains the most common method of treatment in Sub-Saharan Africa. Such chlorination is often associated with emergencies and disease outbreaks. In areas where HWT use (typically chlorination) has been sustained this has been largely as a result of focused social marketing efforts or driven by non-governmental organization intervention programs. While both imported and locally manufactured filters are available, their use is not widespread. The former are typically membrane, siphon[1] or combination filters, while the local filters mainly comprise biosand[2] and ceramic pot filters.

BOX 9
Strengthening regulation in Ethiopia

Under the umbrella of the 'One WASH Programme', which aims to achieve universal access to water, sanitation and hygiene (WASH), the Government of Ethiopia has set a target to increase access to HWT and safe storage to 77 %, by 2015. However, with only an estimated 9.1 % of the population reporting using HWT and safe storage, this target will not be achieved. Part of such efforts will necessitate strengthening regulation which does not include performance testing and is limited in scope to assessing the constituents of chlorine-based products. Other key areas that need addressing include product labelling, clear responsibilities among the different Government laboratories, ministries and regulatory bodies, lessening the time and burden of registering new products and support for use and evaluation of HWT in the field. WHO seeks to support Ethiopia in addressing a number of these issues and has started with technical training of laboratories to assess performance.

The regulatory environment

The data reviewed for some of the countries suggests that while HWT products are regulated in some form, such regulation is limited in scope. These findings confirm an earlier WHO survey of HWT policies and regulations which found that of the 22 African countries that responded, only 50 % regulated HWT in any way and only 40 % did any kind of microbiological testing (WHO, 2012). Among the countries that do regulate HWT technologies in some form, such regulation is largely limited to chemical disinfectants and focused on the chemical constituents rather than on performance and ability to remove pathogens of concern (Box 9 and 10).

BOX 10
Supporting implementation of a national HWT Strategy in Ghana

The Ghana National Strategy for Household Water Treatment and Safe Storage was launched in 2014, and seeks to reduce waterborne disease and achieve health for all by 2025. To achieve this, the Strategy seeks to increase awareness and practice of HWT and safe storage and facilitate use of appropriate and effective technologies (Republic of Ghana, 2014). A national HWT and safe storage taskforce has been established to implement the strategy and facilitate the development of HWT performance standards, as well as to develop certification and product labelling system to aid users in making informed purchasing choices. Currently, there is no comprehensive microbiological performance testing and, like Ethiopia, chlorine regulation is done by the national food and drug authority, while filters are reviewed by the national standards authority. WHO is working on developing a plan of action to support Ghana on the identified priorities.

1 Siphon filters rely on gravity to force water through a ceramic filter element. The ceramic filter element is typically attached to a plastic tube or hose, and the siphoning action pulls contaminated water through the filter and tube into a collection vessel.

2 Biosand filters use a combination of physical and biological mechanisms to remove microorganisms from drinking-water. The filter media comprises layers of sand and gravel and a biological layer (schmutzdecke) through which contaminated water passes.

2.1.2 Asia: Estimated use and regulation of HWT

Of the eight countries reviewed within the South-East Asian and Western Pacific regions, HWT use ranges from 8 % in Bangladesh to 87 % in Viet Nam (Annex 2). Boiling is, by far, the most common method of HWT, followed by filtration. The filter market has grown significantly in China, Vietnam (Box 11) and India (Box 12) in particular.

BOX 11
Rising filter markets and public-private partnerships in Viet Nam

While boiling is reportedly practiced by over 80% of the population, the use of filters has tripled over the past four years and is now reportedly used in 17 % of households. The growth in the use of filters is attributed, in part, to an increased awareness and desire by consumers for safer water through use of HWT. Additionally, the waiving of import taxes for products from certain South Asian countries under the Regional Free Trade Agreement allows imported filters from countries like South Korea and China to be highly competitive. In turn, filters are widely available in supermarkets and trade shops in urban and peri-urban areas. Key challenges are the weak markets in remote areas, and achieving correct and consistent use of HWT. To address these challenges, the government is working with key partners and stakeholders including UNICEF to promote Public Private Partnerships for HWT and safe storage in remote rural Viet Nam.

The regulatory environment

As with the African countries reviewed, HWT regulation in Asian countries is generally weak. Among the seven countries reviewed, only two have a vetted and funded regulatory mechanism that is in place or is being established (Annex 3). There are some encouraging examples, however, where there is growing recognition of the need for regulation of products.

BOX 12
Consumer demand for HWT regulation in India

With the growth of the filter market in India, consumers are also demanding greater product safety and regulation. India recently developed harmonized national HWT evaluation protocols, although product testing under these protocols is currently voluntary. However, there is increasing pressure from consumer advocate groups that testing become mandatory to protect consumers from spurious product claims.

2.2 Scaling up use of quality assured HWT products

Beyond verifying the microbiological performance of HWT products, a number of parallel efforts at the national level are necessary to ensure that potential health gains from HWT are realized. The three main priorities to support scaling up of quality assured HWT products are:

- stronger and more comprehensive regulations;
- increasing availability of quality HWT products; and
- broader enabling environment support including use of targeted market approaches, smart subsidies, and consumer understanding and behaviour change[1].

1 These priorities were discussed and agreed to at a WHO HWT and safe storage strategic meeting held in March 2015 in Netherlands. The meeting report can be downloaded here: http://www.who.int/household_water/scheme/applicant/en/

Much of this work is being undertaken in partnership with a range of stakeholders, including the participating organizations of the WHO/UNICEF International Network on Household Water Treatment and Safe Storage (Box 13).

BOX 13
WHO/UNICEF International Network on Household Water Treatment and Safe Storage: working to increase health gains from HWTS

The Network brings together over 140 implementing agencies, donors, academics and governmental organizations in working towards the common goal of protecting health through safe water. Among the many activities of the Network is communication and knowledge exchange through webinars and online courses. One such course has been developed by the Swiss Federal Institute of Aquatic Science and Technology with support from various Network partners, including WHO. The course can be accessed at: www.coursera.org/course/hwts

2.2.1 Strengthening regulation

WHO is encouraging all Member States to fast-track certification of products that have been tested under the Scheme. In addition, WHO is developing training packages and piloting their use with national laboratories in conducting complimentary testing of HWT products, especially local ones that would not be tested under the international Scheme (Box 14). Finally, WHO is working to develop best practice tools for assisting countries in strengthening their regulatory structures, including improving the labelling of products to enable more informed choice.

BOX 14
Strengthening testing of local products in Ethiopia

WHO is working with national laboratories in Ethiopia to strengthen the technical capacity of laboratory staff in testing local HWT products, including testing against a wider range of pathogens and exploring a variety of candidate microbes under different environmental conditions and technologies to support simple protocol development. The first of these training workshops was conducted in August 2015, and the modules can be accessed at: http://www.who.int/household_water/scheme/en/

2.2.2 Increasing availability of quality HWT products

Increasing access to quality HWT products involves both reducing the costs and time of importing internationally recognized products and improving the quality of locally manufactured products. In some situations, such as conflict zones or after natural disasters, locally procured products may be the only option. Such products are largely filters (ceramic, mineral pot and biosand) but may also include others such as flocculant-disinfectants and sodium hypochlorite solutions. The performance of such local products can vary widely depending on the manufacturing process (Box 15). Thus, WHO is working to understand the key variants affecting performance and strengthening quality assurance and quality control at local manufacturing plants through implementation of best manufacturing practices checklists and frequent spot-check testing of products. This involves working with partners such as the Ceramics Manufacturing Working Group and the Centre for Affordable Water and Sanitation Technology and its partners.

Increasing access also involves understanding where, and by whom, HWT is used and better targeting of resources. To support field monitoring and use of monitoring data to improve programme implementation, WHO and UNICEF developed a toolkit which provides an overall framework for planning, conducting, and utilizing monitoring and evaluation to inform smarter HWT and safe storage implementation. The focus of the toolkit (WHO/UNICEF, 2012a) is on easily assessed measures of use that can be done through observation and chlorine residual assessments. WHO is working with partners in the aforementioned Network to implement and share results from use of the toolkit. In addition, WHO is exploring how to establish national consumer feedback mechanisms to facilitate collection and action on information regarding the ongoing performance of HWT products.

BOX 15
Strengthening manufacture of quality local products

Locally manufactured technologies are often difficult to evaluate in a global scheme because of variability in manufacturing processes, materials used, etc. Evaluating the performance of biosand filters (BSFs) presents a particular challenge due to the relatively long period required for pre-conditioning prior to testing. Therefore, while BSFs have not been evaluated in Round I of the Scheme, they are an important HWT option to consider. Health impact studies have found that BSFs generally reduce diarrhoea (Fabiszewski de Aceituno et al., 2012; Stauber et al., 2011; Tiwari et al., 2009; Sobsey et al., 2008). WHO is working with the Centre for Affordable Water and Sanitation Technology and its partners to develop a quality management process for the local production and installation of BSFs worldwide. Some of the activities include developing a process to validate the competency of filter technicians, standardizing sand selection through sand sieve analysis and flow rate control (Davis et al., 2013).

2.2.3 Supporting the broader enabling environment

WHO is engaging with partners who continue to innovate and learn about how to segment the market to reach particular groups, when and where to provide subsidies (defined in Box 16), and how to better understand consumer needs and reflect this understanding through improved design, user support and communication of HWT benefits.

Among the key partners in this area are Antenna Technologies and Aqua for All, who are working on mechanisms to provide safe water to the poor in a sustainable and affordable manner through innovative HWT and safe storage products, and building on user experiences and satisfying user aspirations for convenience, status and aesthetics. Such market innovation starts with suitable products whose effectiveness has been verified and relies, also, on market creation (from sales, retail and sustainable supply chain) that would serve poor populations and promote consistent and correct use of the products. For example, in Conakry in the Republic of Guinea, Antenna Technologies has been supporting widespread production of sodium hypochlorite flasks in both urban and rural areas. Collaboration with last mile delivery companies has enabled access to fairly remote areas and, through social marketing, approximately 3.5 million flasks are delivered to five provinces each year.

BOX 16
Smart subsidies in HWT

Smart subsidies are all subsidies that enhance the markets and do not undercut the profitability of the supply chain – especially the last mile delivery. They include financing through public-private partnership, social marketing campaigns that create markets but do not hamper them, support for research and development, micro-credits, etc.

At a business level, support and innovative financing are important in increasing access to treatment products, e.g. through research and development support, field studies, and social marketing and smart subsidies. Strong enabling environments are critical in order for these approaches to successfully reach significant scale. This requires engagement and clear division of roles between governments and key partners (Heierli and Osborn, 2014) to ensure that effective, affordable and appropriate HWT options become available and that solutions are delivered and used sustainably.

Governments can play a key role in developing and implementing national HWT and safe storage policies and programmes, which are vital for raising awareness and providing the impetus to take action and induce behaviour change (Box 17). The private sector and implementing agencies are critical for delivering the solutions, be it through sale of water treatment products or the last mile delivery in the poorest most disadvantaged households.

BOX 17

Supporting countries in creating enabling environments for HWT and safe storage

Supporting countries in developing and implementing national HWT and safe storage policies and programmes is critical for raising government awareness and providing the impetus to take action. The Network has been assisting in such efforts through regional integration and policy strengthening workshops. Since Phase II of the Network (2011 to date), five regional workshops have been held in East, West and Southern Africa, and South and South-East Asia, involving almost 20 countries. These workshops bring together officials from the ministries of health and water as well as implementers, manufacturers and researchers to exchange ideas and solutions for scaling-up and sustaining HWT and safe storage. One notable outcome from these workshops has been the establishment of national policies on HWT and safe storage by various countries, including Ghana, Kenya and Tanzania.

3. Conclusion and lessons learned

The findings of Round I highlight three important points. First, a number of products were found to meet WHO recommended performance criteria. Second, not all products perform equally and there are several instances of overstatement of claims and unclear use instructions which may mean such products have limited or no public health benefit. Third, many low-income countries have limited capacity to verify performance claims or effectively regulate the sale and distribution of products. However, as highlighted from findings of the market assessment, there are countries such as Ghana, Ethiopia and Viet Nam showing strong interest in strengthening regulation, In addition, many HWT partners are working to support enabling environment issues on market development, smart subsidies, consumer understanding and behaviour change to ensure HWT products reach and are used by those that need them the most. Only once all the elements of effective HWT are achieved will the ultimate goal of significantly reducing the burden of disease attributable to unsafe drinking-water be met.

Lessons learned from Round I of the Scheme include balancing the goals of technical rigour, programme efficiency and financial viability. In response, WHO has worked to simplify the testing protocols, to reduce testing costs and better support use of similar protocols in developing countries, all with the view to allow more products to be tested. At the national level, WHO is focusing on sensitizing governments to the broader goals of reducing health risks associated with drinking-water and translating the recommendations in the WHO GDWQ into actionable strategies, targets and community efforts.

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Annexes

Annex 1: The Scheme evaluation procedure

Evaluation of HWT technologies under the Scheme is done according to harmonized protocols. The evaluation may consider existing data, providing that such data have been generated by independent testing laboratories using quality assurance protocols that are similar to those of the Scheme.

Initial screening of dossiers

Evaluation of HWT products under the Scheme is based on a voluntary submission of an EOI and product dossier by manufacturers to WHO. The dossier contains supporting documents and information describing the product and its specifications, its operation and maintenance, evidence of user uptake and strategies for reaching the underserved and those most in need. Invitations to interested manufacturers to submit EOIs are published on the WHO website and through various listservs. The criteria for manufacturers to be eligible to submit an EOI are as follows:

- have an established manufacturing process for market-ready HWT products;
- provide evidence of compliance with ISO 9001:28 Quality management systems;
- use materials in their products for which the properties are well described in regards to their safety and composition; and
- have developed robust and tested operation and use instructions, which are used as the basis for developing product specific test plans.

Evaluation under the Scheme is fee-based, but with subsidies awarded by WHO subject to the availability of funds. The criteria for determining whether a manufacturer is eligible for a subsidy are outlined in the Procedure for Evaluation (WHO, 2014c). Priority products for evaluation under the Scheme are those that are low cost, appropriate for low-income settings, generally 'free-standing' and do not require installation and which only treat sufficient water to serve a limited number of individuals a day (as would be typically used in a household or small public facility such as a tertiary healthcare centre). EOIs that meet these initial screening criteria are selected for review by the Scheme Secretariat at WHO with input and advice from the IAC.

Dossier review

The dossier review seeks to determine whether HWT products meet the WHO performance recommendations, and considers product data and information on safety, performance and user testing, as well as production and quality control processes of their manufacture. Key criteria under consideration include the following:

- Do the existing laboratory data demonstrate that the product meets WHO microbiological performance criteria for all three classes of pathogens?

- Are the details of testing protocols used, and test methods comparable to those of the Scheme?
- Is there sufficient evidence to demonstrate the independence of the testing laboratory and quality management procedures employed?
- Is there demonstrated uptake of the product (e.g. through field studies of acceptability or reported sales volumes)?

Depending on the extent to which the above-mentioned criteria are met, three possible recommendations on how a product will be evaluated may be made:

1. *full laboratory testing:* criteria are not met, and testing against all three pathogen classes at one of the designated testing laboratories of the Scheme is required; or
2. *abbreviated laboratory testing and desk review of existing data:* criteria are partially met, and a combination of testing against one or two of the pathogen classes at one of the designated testing laboratories of the Scheme and review of existing data is required; or
3. *desk review of existing data only:* the criteria are fully met, and no laboratory testing under the Scheme is required[1].

WHO has developed technology-specific test protocols which are then adapted by the laboratories to create specific product needs and use requirements. WHO reviews these product specific protocols and shares them with the manufacturer for comment before testing commences.

Considering the advice of the IAC, WHO communicates the outcome of the evaluation to the manufacturer. A list of all evaluated products and their performance level is published on the WHO website, including the relevant test protocols for each of the technology classes.

The Scheme evaluation protocols

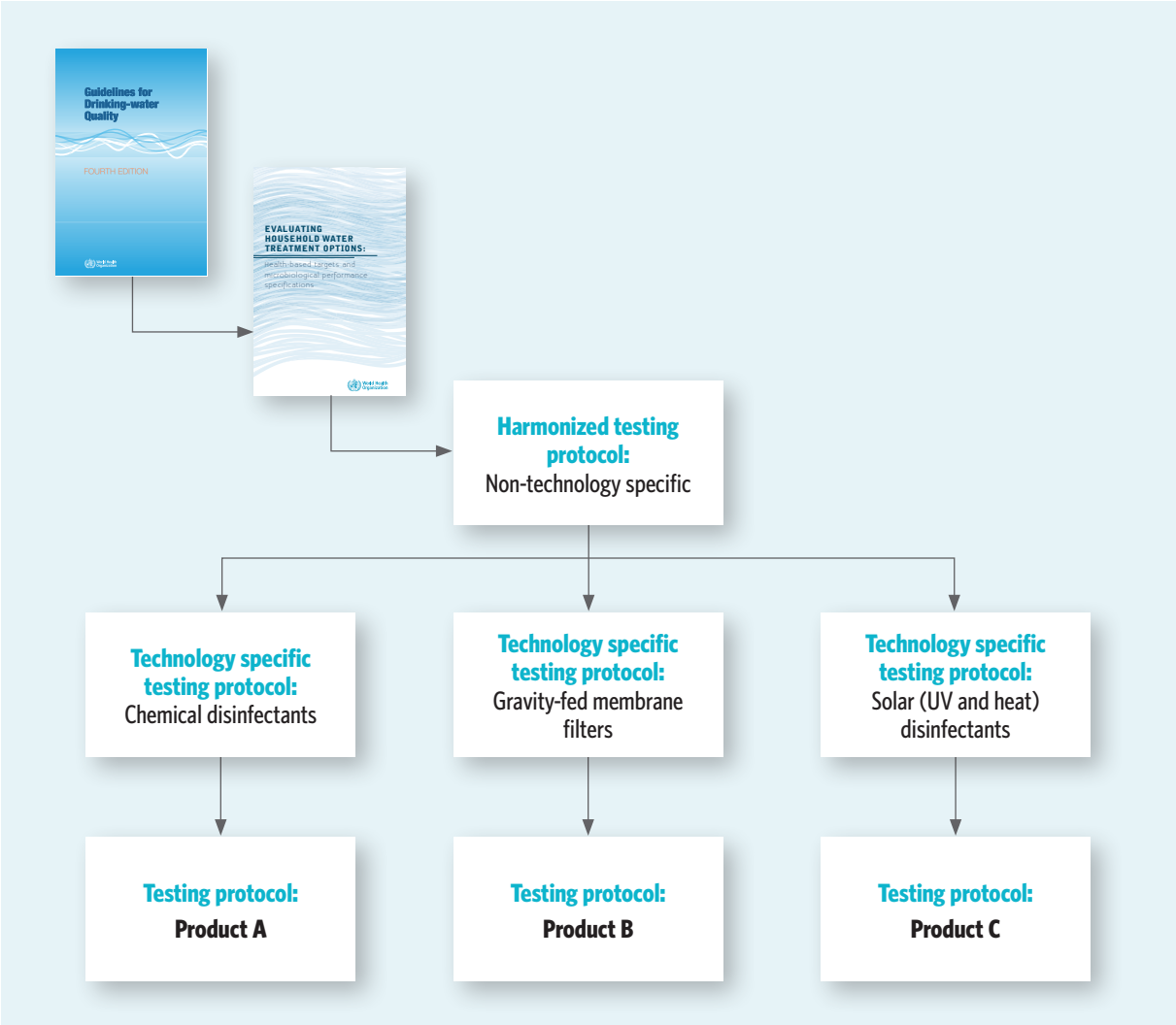
The *Evaluating household water treatment options: health-based targets and microbiological performance specifications* (WHO, 2011a) provides guidance on the development of testing protocols for HWT. It is from this document that the Scheme harmonized and technology-specific testing protocols were developed (Figure A.1).

The harmonized protocol outlines the general testing methods, including number of samples, characteristics of test waters, microbiological organisms, sampling points and reporting formats. However, a wide range of HWT technologies exist (e.g. chemical disinfectants; filtration devices, UV and solar disinfectants) and various parameters such as turbidity, temperature and contact time may influence their microbiological performance (WHO, 2011a). Therefore, based on this harmonized testing protocol, additional protocols that are specific to the various HWT technologies have been developed that take such factors into account[2]. Finally, from these technology-specific testing protocols, the testing protocol for products within the respective technology classes are developed in accordance with the product use instructions.

1 Several products evaluated in Round I have been on the market for some time and had already undergone extensive testing. Thus, evaluation of these products consisted of reviews of existing data only. It is however anticipated that future evaluations of other products will require some testing.

2 The harmonized and technology-specific testing protocols can be found on: http://www.who.int/household_water/scheme/applicant/en/

FIGURE A.1
Overview of the Scheme testing protocols



Test organisms

The reference organisms of the Scheme were selected on the basis of a number of key technical and practical considerations (Table A.1), including evidence of their role and significance in disease prevalence, availability of QMRA data on dose-response relationships in humans and disease burden, sensitivity to HWT treatment processes, cost of purchasing the pathogens for laboratory testing and ease of handling of the pathogens by laboratory staff.

TABLE A.1
Test organisms of the Scheme

Pathogen class	Organism	Key considerations in HWT evaluation
Viruses	MS2 and phiX174 (human viral surrogates)	• Extensively used surrogates for human viruses • Wide variety of characteristics, resulting in varying susceptibilities to treatment • Susceptibility to different disinfectants is well characterized
Bacteria	*Escherichia coli* (faecal indicator organism)	• Well characterized indicator of faecal contamination; frequently found in untreated source waters • Microbial class most sensitive to disinfection
Protozoa	*Cryptosporidium parvum* oocysts (pathogen)	• Relatively resistant to chemical disinfectants such as chlorine, but sensitive to UV irradiation • Readily removed by physical processes such as filtration

In choosing the two virus surrogates, MS2 and phiX174, consideration was given to the wide variety of different viruses' resistance to potential treatment processes (given that viruses vary greatly in terms of size), isoelectric points, type of nucleic acid, presence of lipids and the structure of the proteins in the capsid. Additionally, some treatment systems have more than one mechanism that would remove/inactivate viruses. For example, a filtration system (activated carbon) may be combined with a UV light system. Some viruses may be more easily removed by adsorption to the activated carbon than others, and others may be more resistant to the UV light. For these reasons and as non-pathogenic microorganisms are preferred, two bacteriophages with differing characteristics and responses to treatment processes are used in the assessment of the performance of HWT products, and the virus performance claim is based on the poorest log reduction of the two.

Ideally, surrogates would be chosen for all classes as they are easier and cheaper to use and can more easily be applied to capacity building efforts; two important considerations for making the protocol accessible to range of laboratories. However, at this time, there is insufficient evidence to support selecting surrogates for all classes of pathogens. WHO will continue to review the evidence with the aim of simplifying the testing protocols.

Test waters

Testing under the Scheme is intended to model, as far as possible, the variety of conditions under which HWT products are used, including the quality of source waters. Products are evaluated are against two types of test waters: general test water representing high quality groundwater or rainwater and the non-aggressive phase of testing; and challenge test water with more aggressive water specifications generally representative of surface water (Table A.2).

The distinguishing characteristics for these two waters are the specifications for total residual chlorine, pH, turbidity, temperature, total dissolved solids, total organic carbon and alkalinity[1]. The general test water is not technology-specific, and is the same for all products. The challenge test water, however, is based on the product's technology.

TABLE A.2
Characteristics of general and challenge test waters

	Specification	
Constituent	General test water	Challenge test water
Chlorine (mg/L)	< 0.05	< 0.05
pH	7.0 ± 0.5	Technology dependent
Total organic carbon (mg/L)	1.05 ± 0.95 mg/L	15 ± 5 mg/L
Turbidity (NTU)	< 1 NTU	40 ± 10 NTU
Temp (°C)	20 ± 3°C	Technology dependent
Total dissolved solids (mg/L)	275 ± 225 mg/L	1500 ± 150 mg/L
Alkalinity (mg/L as $CaCO_3$)	100 ± 20 mg/L	100 ± 20 mg/L

Adapted from the Scheme Harmonized Testing Protocol (WHO, 2014b)

1 Details of the test water specifications for each technology can be found on: http://www.who.int/household_water/scheme/applicant/en/

Annex 2: Overview of reported use of HWT in selected countries in Sub-Saharan Africa and Asia

TABLE A.3
Use of HWT in selected countries – Sub-Saharan Africa

Country	Proportion of households reporting HWT use	Estimated population reporting HWT use (in thousands)
Democratic Republic of Congo	4 %	2,488
Ethiopia	9 %	7,926
Ghana	9 %	2,111
Kenya	45 %	18,205
Malawi	28 %	3,348
Mozambique	11 %	2,684
Nigeria	5 %	7,826
Rwanda	49 %	5,277
Sudan	4 %	1,462
Uganda	47 %	15,906
Tanzania	36 %	16,235
Zambia	34 %	4,520

Data taken from the most recent country-level multiple indicator cluster survey or demographic and health survey.

TABLE A.4
Use of HWT in selected Asian countries

Country	Proportion of households reporting HWT use	Estimated population reporting HWT use (in thousands)
Bangladesh	8 %	11,637
Cambodia	74 %	10,673
China	85 % of the rural population boil and 3–5 % of the urban population use filters	1,155,848 (boiling) 67,991 (5 % filter use)
India	33 %	397,856
Indonesia	70 %	168,714
Myanmar	35 %	17,916
Nepal	14 %	2,134
Viet Nam	87 %	77,382

Data taken from the most recent country-level multiple indicator cluster survey or demographic and health survey, Zhang et al. 2009 and Wen, 2011.

Annex 3: Overview of the regulatory environment for HWT

This annex outlines provides an overview of HWT reported use and the policy and regulatory environment for countries reviewed in Sub-Saharan Africa (Table A.5) and Asia (Table A.6). Countries were assessed along five key policy and regulation elements that included:

- inclusion of HWT and safe storage in national policies;
- mandatory regulation of chlorine based HWT technologies;
- mandatory regulation of non-chlorine based HWT technologies (e.g. filters);
- availability of HWT standards and/or certification of HWT technologies; and
- committee/ structure in place at the national level to guide HWT coordination within the country.

These criteria were drawn from a global survey report (WHO, 2012) that assessed countries based on criteria for policy readiness in scaling up HWT. Countries were categorized into three tiers: those with four to five of the above-mentioned elements in place were considered in tier 1, those with three elements were categorized as tier 2, and those with less than three elements were categorized as tier 3.

TABLE A.5
Overview of the regulatory environment for HWT in selected countries in Sub-Saharan Africa

Country	HWT Regulation
Tier 1	
Democratic Republic of Congo	HWT and safe storage is included in national policies and products are regulated. There is a committee/ structure in place for HWT coordination (WHO, 2012).
Ethiopia	Chemicals are regulated by the Ethiopian Food, Medicine, Health Care Administration, while filters are unregulated. HWT and safe storage is included in national policies and a committee/ structure is in place for HWT coordination (WHO, 2012).
Ghana	A HWT strategy has been published with government and private partner roles defined. Ghanaian law does not include regulation of HWT products, however, chemicals are regulated by the Food & Drug Administration. A working group is in place to develop a comprehensive regulatory approach for HWT.
Kenya	HWT and safe storage is included in national policies and products are regulated (WHO, 2012) by Kenya Bureau of Standards (KEBS). However, KEBS's capacity to test and regulate products is limited, given the volume of products coming into the country (Kariuki, personal interview, 2015[a]). Due to porous borders, there are unaccredited HWT products on the market. A HWT and safe storage technical working group is in place to develop a regulatory approach for HWT and to draft monitoring and evaluation guidelines.
Tanzania	HWT and safe storage is included in national policies, and a committee/ structure is in place for HWT coordination (WHO, 2012). Tanzania Standards Bureau certifies HWT and safe storage products and technologies (voluntary standards). Proctor & Gamble and Population Services International note a requirement for registration of products before distribution.
Uganda	HWT and safe storage is included in national policies, and a committee/ structure is in place for HWT coordination (WHO, 2012). Mandatory standards (US 201:2008) for water treated by conventional methods (filtration, chlorination, sedimentation) are provided by the Uganda National Bureau of Standards.
Tier 2	
Mozambique	HWT and safe storage is included in national policies (WHO, 2012) and all products coming into the country are noted as being evaluated by the Ministry of Health (WHO/UNICEF, 2012b).
Nigeria	HWT products are reported as being regulated by the Federal Ministry of Health (Olokun, 2013). Standards/ certification are available and a committee/ structure is in place for HWT coordination (WHO, 2012).
Rwanda	HWT and safe storage is included in national policies, with HWT standards/ certification and a committee/ structure in place for HWT coordination (WHO, 2012).
Sudan	HWT and safe storage is included in national policies, with HWT standards/ certification and a committee/ structure in place for HWT coordination (WHO, 2012).
Zambia	Zambia Bureau of Standards (2014) has specifications for chlorine disinfectants for household water treatment. HWT and safe storage is included in national policies with a committee/ structure in place for HWT coordination (WHO, 2012).

Country	HWT Regulation
	Tier 3
Malawi	HWT is implied by national policies though not explicitly stated (Rowe, 2012). The Catalogue of Standards developed by the Malawi Bureau of Standards includes standards regarding control and surveillance of drinking-water networks and bottled water but does not include criteria for water treatment products (Rowe, 2012, Malawi Bureau of Standards, 2015).
South Africa	HWT and safe storage is not included in national policies and there is no standing committee in place for coordination of HWT (WHO, 2012). Requirements for drinking-water treatment units to meet microbiological and other standards are specified (South African Bureau of Standards, 2006).

[a] John Kariuki, Chief Public Health Officer, Ministry of Health, Kenya (retired)

TABLE A.6
Overview of the regulatory environment for HWT in selected countries in Asia

Country	HWT Regulation
	Tier 1
India	HWT specific testing standards for chemicals and filters were issued February, 2015. Currently, standards are voluntary, though advocacy groups and WASH stakeholders are working towards making testing and certification mandatory (Labhastewar[a], personal interview, 2015). The Bureau of Indian Standards provides product certification.
Viet Nam	HWT and safe storage is included in national policies. Chemical disinfectants are regulated by Ministry of Health. Standards/ certification are available for HWT and safe storage technologies, and a committee/ structure is in place for HWT coordination.
	Tier 2
Bangladesh	HWT and safe storage is included in Bangladesh WSP. The Bangladesh Standards and Testing Institution provides voluntary certification and a committee/ structure is in place for HWT coordination (WHO, 2012).
Cambodia	Cambodia reports that HWT policies are included in national policies and a committee/ structure is in place for HWT coordination. There is no mandatory regulation of HWT products or certification standards (WHO, 2012) but standards are in the process of being finalized for HWT and safe storage technologies (Rosenboom, 2010).
Indonesia	HWT and safe storage is included in national policies with a committee/ structure in place for HWT coordination (WHO, 2012). Flocculant-disinfectants such as P&G Purifier of Water are registered with the government.
	Tier 3
Myanmar	No information on regulation of HWT products, inclusion in national policies, or standards for HWT technologies could be found.
Nepal	Nepal reports HWT policies are included in national policies and a committee/ structure is in place for HWT coordination. There is no mandatory regulation of HWT products or certification standards (WHO, 2012).

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