



**Meeting of the Independent Advisory Committee to the WHO
International Scheme to Evaluate Household Water Treatment**

25-26 June 2013
Geneva Switzerland

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1. Introduction

There are a number of different household water treatment and safe storage methods (HWTS), including chemical disinfection, disinfection with heat, filtration and flocculants/disinfection. Achieving health gains requires use of a method that sufficiently reduces pathogens to protect health. To guide such health-based decisions, WHO recently published recommended criteria for evaluating and assessing the performance of HWT (including three levels of performance, i.e. “highly protective”, “protective” and “interim”)¹. As governments increasingly address the use of HWT in national policies and health programmes, and while manufacturers continue to promote and distribute HWT technologies, there is a pressing need for objective and health-based evaluation and regulation of HWT.

Based on the above mentioned WHO performance recommendations, a WHO International Scheme to Evaluate HWT (“HWT Scheme”) was established in 2013. The main aim of the Scheme is to guide WHO Member States and procuring UN Agencies in the selection of technologies and support national governments in a number of evaluation related functions. One of the key components of the Scheme is the Independent Advisory Committee (IAC). The IAC will provide advice to WHO on a number of aspects, including criteria for the selection of the testing laboratories, harmonized testing protocols and review and advice to WHO on the testing results of devices submitted to the Scheme for evaluation. For further details on the Scheme and the ToR of the IAC refer to Annex 1.

A first meeting of the IAC was held 24-25 June at WHO HQ to discuss a number of technical items including the testing of HWT and review of test results. This report summarizes the meeting discussion and decisions taken.

2. Meeting overview and objectives

The Meeting of the IAC provided the opportunity for newly nominated members to discuss a number of key technical issues regarding the initial phase of the HWT Scheme. In advance of the meeting IAC members were provided the draft technology test protocols and draft test reports for review and consideration. The members of the IAC and WHO staff that attended the meeting are found in Annex 3.

¹ *Evaluating household water treatment options: health-based targets and microbiological performance specifications*. World Health Organization, 2011.
http://www.who.int/water_sanitation_health/publications/2011/household_water/en/

The objectives of the meeting were as follows:

- Discuss draft harmonized testing protocols and agree on revisions for finalization
- Determine quality control/quality assurance mechanisms for testing laboratories
- Discuss initial round of testing, including call for submissions, prioritization of products to be tested, reporting templates, and timeline
- Determine how to handle products that have already been tested to national standards (i.e US Environmental Protection Agency)
- Develop priority list of key country capacity activities regarding strengthening regulation and evaluation

Refer to Annex 2 for the meeting agenda.

3. Key discussion items

There were several key issues that were discussed during the meeting. These are summarized according to the following topics: harmonized testing protocols; submission and assessment of product documentation; interim category addressed; WHO final recommendations and communication of result; capacity building; and on-going monitoring of listed products.

Harmonized testing and protocols

- *Designated testing laboratories*

WHO summarized the process for identifying laboratories to conduct testing under the Scheme. In short, WHO developed an initial list of potential of laboratories based on input from Regional Offices, the Advisory Group for the WHO/UNCIEF International Network on Household Water Treatment and Safe Storage and by consulting the WHO global database of laboratories (GLaD Map). Among these five were shortlisted and two, based on the criteria set forth in the Scheme Framework (Annex 1), were recommended. These were: NSF International (USA) and KWR Watercycle Research Institute (the Netherlands). For the initial start-up phase of the Scheme, it was agreed that WHO would designate, at most, two testing laboratories; each in a different geographic region. Other WHO evaluation schemes only have one or two laboratories as experience indicates that several laboratories complicates issues concerning comparability of results (especially given the intra-species variability of microorganisms), coordination, as well as differences in laboratory testing costs.

It was agreed by that these laboratories would be competent to carry out the necessary functions of testing. The IAC also suggested to periodically re-assess their performance. Finally, it was discussed that in the future, depending on demand for testing under the Scheme and the improvement of technical capacity of other laboratories, to consider including additional laboratories from Regions where HWT is most widely used (i.e. Africa, Asia or South America).

- *Develop a generic protocol that covers key elements (test water, surrogate microbes for each pathogen class/treatment type, sampling schedule, etc) and make this available on the WHO website.*

It was agreed that a single generic (non-technology specific) protocol is necessary. This protocol would identify the key elements to consider (test water characteristics, organisms, etc) in the testing of technology performance and would be important for understanding the general test approach. The generic protocol would also provide mathematical formulas and example calculations for estimating (mean) log-removals. The protocol would also address issues concerning how to handle data that is below the limit of detection. Technology specific protocols will be included in the appendix of the generic test protocol. It was agreed for purposes of the HWT Scheme designated laboratories are to make use of the same test surrogate organisms for each organism class. These were initially identified as *E. coli* for bacteria, *Cryptosporidium parvum* for protozoa, and two or three bacteriophages for viruses, yet to be identified. In effort to identify bacteriophages appropriate for the testing, a literature review is being conducted by the IAC on candidate phages. Phages will be selected based on their relevance to human pathogenic viruses and consideration of their behavior under different treatment processes.

All technologies will be tested for all three classes of organisms at concentrations that would allow for the demonstration of the highest performance tier ‘*highly protective*’. It was also agreed that it was not necessary to include stagnation testing, unless there is convincing evidence of pathogen re-growth, where a new surrogate may also be required. In addition, to simulate total organic carbon (TOC) conditions in two different test waters, it was suggested that only humic acid (and not tannic acid) should be used. To allow for consistent testing between and among HWT Scheme laboratories, all test water characteristics are to have ranges for each specification.

- *Technology specific testing protocols*
The IAC reviewed twelve draft technology specific test plans for the following technologies: chlorine, iodine, and copper/silver disinfectants, filtration, halogenated (non-iodine) resins, iodinated resins, and ultraviolet (UV) light. They

recommended that only one generic plan, as described above, should be developed. This generic plan would to the extent possible address issues covered in the specific test plans with technology specific appendices added as needed. Furthermore, the IAC identified the following additional technologies that may require specific test plans to be developed and reviewed for consistency with the above, before the first call for submissions. These include: solar batch treatment; reverse osmosis; a combined technology of silver/copper with granular activated carbon (GAC). The WHO recommendations are intended to address all technologies. Therefore, appendices will be added as needed to the general protocol, to allow for technologies or combinations of technologies not currently identified so as to encourage innovation.

- *Surrogates*

The validation of the suitability of coliphages as surrogates in HWT testing was identified as a priority. Validation will investigate the suitability of surrogates to measure the treatment of virus sized particles and how well those surrogates represent human pathogens. Existing data will be summarized by Prof Gerba and made available to WHO and the IAC. In addition, *Cryptosporidium* is an expensive and often difficult to source organism, particularly in higher concentrations, therefore a longer term goal will be to identify an alternate organism to *Cryptosporidium* for the protozoan class.

Submission and assessment of product documentation

- *Clarify the criteria for acceptance of testing under the HWT International Scheme.*
The process for seeking products to be tested was discussed. WHO will issue a call for Expressions of Interest on the website and through both the International Network on Household Water Treatment listserve and the Water, Sanitation, Hygiene and Health Unit listserve. Manufacturers will reply by submitting the necessary information, including product documentation. It was suggested that WHO may charge a nominal fee to review applications but the transaction costs of this need to be further investigated. WHO with input from the IAC will then review the product documentation and decide whether a product can be accepted for testing by a designated testing laboratory.

A reference sheet will be created for manufacturers to provide guidance on submission criteria. The factors to be considered in deciding whether or not a technology should be accepted for testing include: already identified technologies; validity of technical processes employed to remove microorganisms; description of the methods used and results from microbiological testing data (initial and lifetime

testing); disclosure, characterization and safety information for all materials that are in contact with water (e.g., Material Safety Data Sheets, MSDS, or international equivalents)²; use instructions; data on the release of chemical with temperature, where appropriate (chlorine and iodine); production capacity; and quality assurance/quality control of manufacturing process. Following the initial review, applications will receive one of the following decisions: test under the Scheme or a request to revise one or more aspects of the application (use instructions, more detailed description of the materials, etc.) and resubmit for consideration. Manufacturers that fail to submit all required materials and/or fail to pay the requested fee will not have their products tested. If more products are submitted for review than can be accommodated by the laboratories for testing, priority shall be based on a first come, first serve for each Round. A summary of the initial review will be posted on the WHO website.

- *Consideration for products previously tested*

It was agreed that products that have been previously tested by a laboratory that meets those criteria outlined in the HWT Scheme Framework and is comparable to the designated testing laboratories may submit full documentation of the product and the testing methods and raw data to WHO. Based on the results the product would be categorized in one of the three WHO performance categories. If further testing is needed to demonstrate meeting the most rigorous category (“highly protective”) the product would be sent to one of the designated testing laboratories. The fee for such a review would be assessed by WHO on a case by case basis.

- *Prioritization of products for subsidized testing*

Recognizing that small manufacturers in developing countries may not be able afford the full cost of evaluation, a reduced testing fee may be levied. Such reduced fees are subject to availability of funds. The criteria for determining whether a developing country manufacturer is eligible for a reduced testing fee will be based on size and capital resources of the manufacturer, annual turnover (the greater the turnover, the less need for subsidy), country of origin/location where company registered with priority to those countries where safe drinking-water is least accessible, cost per litre of treated water delivered on site, and plan for scale-up, application, and distribution.

- *Assessing manufacturer demand*

Given the Scheme is still in the start-up phase and it is not completely clear the potential demand from manufacturers to submit devices for testing, it was agreed

² For materials for which safety sheets do not exist (i.e. locally sourced sand), safety will be considered on a case-by-case basis.

that an informal survey should be done to gauge interest and ability to pay for testing. This will allow WHO and the designated testing laboratories to better plan for Round I of testing. Based on informal discussion with manufacturers it is estimated that between 5-10 manufacturers will submit for Round I of testing. WHO will conduct such a survey through the International Network on Household Water Treatment and Safe Storage and report back to the IAC on the results.

Interim category addressed

- *'Interim' category name change and change in data required for claim*
It was decided that the claim of *interim* did not communicate a clear message. As such, '*interim*' will be replaced with '*limited protection*'. Given this category only requires that the product meets the performance targets for two classes of organisms in the middle category of 'protective' it was deemed necessary to specify for which organism class the product is not protective. In addition, products which meet the '*limited protection*' category shall also be required to include a statement of what is required to protect against all classes of pathogens. For example, a chlorine based product which does not remove cryptosporidium may carry the claim: "*does not remove cryptosporidium, additional protection recommended: membrane or ceramic filtration.*" Regardless of the expected performance level, testing for all products shall be done against all three classes of organisms.
- *Data requirements changed for limited protection (interim) claim*
The category of *interim* (now called '*limited protection*') was included in the WHO recommendations primarily for, although not limited to, chlorine products. There was consensus that sufficient health impact data on known chlorine products currently being used in the field exists and no additional epidemiological data would be required for such chlorine based products. Any information the manufacturer has on health impact data will be considered in the review of the product. However, if a new product is under consideration and test results demonstrate that the product only meets *limited protection*, the manufacturer will be required to also provide evidence of health impact. The extent of evidence needed will be conducted on a case by case basis with consultation with the IAC.

WHO final recommendations and communication of results

- *Review and posting of results*
It was agreed that there is value in providing a summary of review for all product testing irrespective of performance outcome (achieving a performance claim level or failing), therefore all results shall be posted on-line. The specific mechanisms of

treatment may not be fully disclosed on the online report form if the product functions according to a proprietary, not publicly available process. For each round, results will be posted once all testing is complete.

- *Labelling/communication of performance*

Based on test results, products meeting the WHO performance tiers will be classified as follows: *highly protective, protective, and limited protection*. The language and parameters of the label will be held to internal WHO rules and regulations. The WHO logo will not be used on any product. Technical descriptions of the product may include mention of WHO testing and reference to the WHO HWT Scheme website. A 'labeling criteria' reference guide will be created to ensure labeling requirements are met. WHO with input from IAC and the WHO Legal Office will review labelling of all tested products.

Capacity building

- *Communication of Scheme and capacity building activities.*

The primary form of communication regarding the Scheme will be the WHO website. A Q&A section on the HWT website or informational webinar was recommended as a cost-effective option for broad outreach. In addition, hosting a stakeholders meeting with key UN agencies, donors, and government to discuss the Scheme and gather input on key capacity building activities was suggested. One important goal is to build the capacity of national laboratories to conduct more rigorous evaluations of HWT in-line with WHO recommendations. Such laboratories may become future designated testing laboratories and/or meet demand for testing of local products that may not be evaluated by the Scheme. Any Scheme designated laboratory would need to meet the criteria of ISO 17025 compliance, agree to let the WHO own the data, and be willing to conduct testing at cost.

Connecting with WHO hosted Networks, specifically the Regulators Network and the WHO/UNICEF International Network on HWTS (Network), provide two means offer two by which to engage key stakeholders in capacity building activities. A recent national workshop held in Ethiopia that sought to streamline and strengthen the regulatory process while identifying concrete steps to improve the rigour of testing of HWT provides an example of recent Network activities in this area³.

On-going monitoring of listed products

- *Continued qualification based on initial testing*

³ WHO, 2013. Ethiopia workshop on evaluation and regulation of household water treatment. http://www.who.int/household_water/resources/en/

No scheduled reassessment of listed products will be required, unless there are changes to the product, product materials, or manufacturer, including transfer of rights between manufacturers. If there are no changes, every three years the submission of a letter indicating that there has been no change to the product, process, or ownership of the manufacturing will be required. If there are changes, any changes that may affect product performance (change to material supplier, process, location of manufacture, etc.) or ownership of manufacturing require notification to the WHO for a review. WHO with input from IAC will decide if such changes warrant additional testing. For products with a long working life, longevity of performance testing may be required based on review of the IAC.

- *Complaint from the field*

In the event of a complaint from the field, the complaint will first be assessed by WHO and, if needed, will be reviewed by the IAC and may require assessment of a product (not listed) or re-assessment of a product that was previously assessed (listed).

4. Action items and next steps

At the conclusion of the meeting, all members agreed to work on the recommended key action items. These items include: summary of candidate bacteriophages, development and finalization of the WHO agreements with the designated testing laboratories, finalization of the testing protocols and report, finalization of the calls for submission, survey of interest in testing from manufacturers, and development of immediate plan for capacity building activities in priority countries. Dr. Gerba shall provide a summary of the coliphages to the IAC by mid Q3 2013. WHO shall secure the agreements with the designated laboratories in Q3 2013. WHO shall finalize the testing protocols and report, finalize the calls for submission and develop and distribute the manufacture expression of interest surveys late Q3 2013.

It was agreed that assuming the testing protocols and agreements with the laboratories are finalized and approved the first call for submissions would occur in Q4 2013. The IAC will review initial submissions remotely and then re-convene in Geneva in Q1 or Q2 2014 to review the first round of testing results.

Framework for the International WHO Evaluation Scheme for Household Water Treatment (HWT) Technologies

Introduction

The number of diarrhoeal deaths associated with unsafe drinking-water and inadequate sanitation and hygiene is alarmingly high (WHO, 2012). Vulnerable populations, including young children, people living with HIV and malnourished populations are especially at risk. After pneumonia, diarrhoea is the second leading cause of death among children under five years of age (Black et al., 2010).

Household water treatment (HWT) provides an interim measure for removing pathogens from drinking-water and reducing disease risk, particularly where access to safe drinking-water supplies is not available or inconsistent. Recent meta-analyses (Fewtrell et al., 2005; Waddington et al., 2009) reported a 35% and 42% reduction in diarrhoeal disease, respectively, associated with HWT. As such, HWT is included as one of seven components of the WHO/UNICEF comprehensive strategy on diarrhoea control (UNICEF/WHO, 2009). Furthermore, a number of international targets call on governments to address the importance of HWT in national policies and strategies and through intersectoral task forces (WHO/UNICEF, 2011).

Achieving health gains associated with household water treatment depends on two key requirements. First and foremost, HWT technologies must sufficiently reduce pathogens to protect health. Second, such technologies must reach and be consistently and correctly used by the populations most at risk for waterborne disease. As governments increasingly address the use of HWT in national policies and health programmes, and while manufacturers continue to promote and distribute HWT technologies, there is a pressing need for objective and health-based evaluation and national regulation of HWT to ensure expected health gains are achieved.

In order to assist Member States in the evaluation and selection of HWT, WHO recently published a document detailing global criteria and guiding principles for evaluating and assessing the performance of HWT⁴. This document provides a framework for assessing the performance of HWT against the aforesaid criteria and classifies them into three levels of performance (“highly protective”, “protective”, and “interim⁵”) based on their ability to remove pathogens.

⁴ The criteria are based on microbial performance of HWT and are detailed in the following document: WHO, 2011. *Evaluating household water treatment options: Health-based targets and microbiological performance specifications*. World Health Organization, Geneva.

⁵ To better reflect the performance of devices in the “interim” category, this category has been re-named as “limited performance”. For more details see the June 2013 meeting report of the Independent Advisory Committee to the WHO Scheme to Evaluate Household Water Treatment Technologies.

2. Basis for a household water treatment evaluation scheme

There are a number of different HWT methods that aim to reduce microbial pathogens. The following summarizes the main types of HWT methods (Sobsey, et al., 2008):

- physical removal of pathogens (e.g. filtration, adsorption, or sedimentation);
- chemically treating water to kill or deactivate pathogens, most commonly with chlorine;
- disinfection by heat (e.g. boiling or pasteurization) and ultraviolet (UV) radiation, either using the sun (solar disinfection) or an artificial UV lamp; and
- combination of these approaches (e.g. filtration or flocculation combined with disinfection).

These different treatment methods vary in their ability to remove the main classes of enteric pathogens that pose health risks (bacteria, protozoa and viruses) and, even within each of these treatment categories, performance among different specific technologies varies considerably.

While the aforementioned WHO recommended criteria and guiding principles for evaluating and assessing the performance of HWT have been distributed to all WHO country offices, ministries of health and ministries responsible for water resources, many Member States have neither the capacity, nor the resources to evaluate technologies based on WHO's recommendations. Concurrently, these same governments, mainly located in sub-Saharan Africa, Southeast Asia and parts of Central and South America are increasingly being approached by both local and international manufacturers to buy and/or allow the sale of their product within the respective countries. This presents a serious dilemma. To realize the health gains of HWT, technologies must meet the WHO criteria and be correctly and consistently used. An international evaluation scheme for HWT would serve to fill this immediate and growing need for a rigorous health-based assessment of HWT technologies.

WHO, as the global authority on international public health, is ideally suited to coordinate global efforts evaluating household water treatment products. In this regard, it should be noted that WHO has experience in coordinating public health evaluation schemes, for example in the field of pesticides and rapid malaria diagnostics.

3. Scheme Objectives

There are two main objectives to the Scheme. These are:

- promote and coordinate independent and consistent testing and evaluation of household water treatment products based on WHO criteria, and in so doing, guide WHO Member States and procuring UN Agencies in the selection of HWT;

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

An overview of the evaluation scheme for HWT is provided in **Table 1**.

Table 1. Overview of HWT Scheme

Step 1. Submission and assessment of product documentation	<p>In response to a call for Expressions of Interest issued by WHO, the manufacturer sends an application and product documentation to WHO; WHO reviews the product documentation and decides whether a product can be accepted for testing by a designated testing laboratory.</p> <p>Upon submission of a product for testing under the Scheme, the manufacturer will be required to enter into a Materials Transfer and Confidentiality Agreement with WHO, pay WHO the fixed fee for the management of the Scheme and the cost of laboratory testing, and send product(s) to the testing laboratory designated by WHO. The Materials Transfer and Confidentiality Agreement is discussed in further detail in Section 4.3.</p>
Step 2. Product evaluation by participating laboratory	<p>Laboratory evaluates product in accordance with the agreed procedure, using the harmonized protocols and reporting templates for testing results; laboratory submits final testing report to WHO within 90 days of signature of a Technical Services Agreement with WHO and receipt of the required product units and funds for testing. The testing results and reports will be owned by WHO, and the laboratories will be bound by adequate confidentiality obligations, including protecting confidential information of the manufacturers.</p>
Step 3. Review by Independent Advisory Committee (IAC)	<p>IAC reviews testing results and provides recommendation to WHO on level of performance (i.e. “highly protective”, “protective” or “limited protection”). Annual meeting to review testing results and maintenance of evaluation status and tele/video conferences held regularly to discuss other issues as they arise.</p>
Step 4. WHO final recommendations	<p>Considering the advice of the IAC, WHO publishes on the WHO website for those products that were found to meet the WHO recommended criteria:</p> <ul style="list-style-type: none"> - the full testing reports (subject to the protection of confidential information); and - a list of all tested devices and their performance level. <p>The above will be accompanied by appropriate notes and disclaimers. WHO will also communicate the outcome of the evaluation to the manufacturer and test laboratory.</p>
Ongoing Maintenance of evaluation status	<p>A listed product will not be reassessed, unless there is a change in circumstances which may affect the performance of the product (i.e. new manufacturing processes or change of material supplier) or unless there is a complaint from the field or in the event that fraud or omissions by the manufacturer becomes apparent. Every 3 years the manufacturer will be required to submit documentation to verify there have been no major changes in circumstances.</p>

4. Main steps of establishing and managing the Scheme

The main steps of establishing and managing the Scheme are discussed in further detail below. They include:

- establishment of the secretariat for the Scheme at WHO and establishment of the IAC;
- development and finalization of the criteria for the selection of the testing laboratories, the evaluation and testing procedure, template call for submissions and prioritization criteria, harmonized testing protocols and reporting templates;
- selection of designated testing laboratories;
- call for manufacturer submissions;
- evaluation of submitted product documentation by WHO with a view to determining whether a product can be accepted for testing by a designated testing laboratory;
- testing of products by the designated testing laboratories;
- evaluation of testing results by the IAC and advice to WHO on the level of performance of the submitted devices (“highly protective”, “protective” and “limited protection”), and publication by WHO on the WHO website of the full testing reports (subject to the protection of confidential information) and a list of all tested devices and their performance level;
- maintenance of evaluation status, changes in manufacture and control, complaints, new information, etc.; and
- complimentary country capacity building activities, including building capacity in conducting complimentary national assessments of HWT in the field and strengthening national regulation of HWT.

4.1 Establishment of the secretariat for the Scheme and IAC

A secretariat for the Scheme has been established at WHO/WSH to issue calls for manufacturer submissions, to review product documentation and decide whether a product can be accepted for evaluation by a designated testing laboratory, to arrange and coordinate the meetings of the IAC, and more generally, to manage the day to day operation of the Scheme.

WHO/WSH will establish the IAC for advice to WHO on the criteria for the selection of the testing laboratories, the evaluation and testing procedure, harmonized testing protocols and reporting templates for testing results, call for and prioritization of submissions, etc., and for review and advice to WHO on the testing results of devices submitted to the Scheme for evaluation. Terms of Reference for the IAC can be found in **Appendix 1**.

In order to ensure the self-sustainability of the Scheme, WSH will use a cost recovery system pursuant to which all participating manufacturers will, at the time that their product is accepted by WHO for testing, be required: (i) to pay a fixed fee as a contribution towards the managerial cost of the Scheme; and (ii) to cover the cost of the testing of their product by the testing laboratories. The fee and testing costs may be set at a lower level for those manufacturers of developing countries for whom the total amount represents an obstacle to participate in the

Scheme. More details on criteria for providing subsidies to manufacturers can be found in the 2013 meeting report of the Independent Advisory Committee to the WHO International Scheme on Evaluating Household Water Treatment Technologies.

4.2 Designation of testing laboratories

Based on the recommended criteria for the selection of the testing laboratories, WHO/WSH will establish a network of participating institutions who will conduct the testing of the devices in accordance with the agreed procedure, using the harmonized protocols and reporting templates. Criteria for the selection of participating testing laboratories are attached as **Appendix 2**. Testing laboratories should preferably be institutions of which a department has been designated as a WHO Collaborating Centre (it being understood that the testing work would not be conducted by the institution as part of the WHO CC terms of reference or work plan).

Division of labor between the participating institutions will be based on the relative proximity to the manufacturer of the product to be evaluated, equity in distribution of workload, and availability of participating institution to complete the evaluation within the time required.

4.3 Call for manufacturer submissions

WHO will issue regular calls for submissions from manufacturers. Through each call, manufacturers of a certain category of HWT will be invited to submit their devices and supporting technical documentation to WHO. The calls for submission will be published on the WHO website and included in relevant newsletters⁶. All manufacturers will be required to submit detailed documentation on their technologies and to demonstrate that a minimum level of performance has been achieved, as a condition for participation in the Scheme. As advised by the IAC, products will be prioritized based on a first come, first serve basis and meeting all the aforementioned criteria for submission.

WHO will review the product documentation provided by the manufacturer to verify whether it is complete and that a minimum level of performance has been demonstrated, with a view to deciding whether the product can be accepted for testing by a designated testing laboratory.

Those manufacturers that have had their product tested by one of the designated testing centres prior to the establishment of the Scheme will be invited to include the testing results in product documentation submitted to WHO. WHO will send these testing results to a designated testing laboratory for review and determination whether additional testing based on the harmonized protocol and against the WHO recommended criteria and performance specifications is necessary. For example, additional microbiological challenge testing would be needed to determine whether a device that has been found to meet NSF International's⁷ minimum log reduction of 6/4/3 for bacteria, viruses and cysts, also meets WHO's "highly protective" level of performance of 4/5/4 log reduction for the same three classes of pathogens.

Upon submission of a product for testing under the Scheme, each manufacturer will be required to:

⁶ WHO Water, Sanitation, Hygiene and Health Newsletter, UNICEF/WHO International Network on Household Water Treatment and Safe Storage Newsletter.

⁷ NSF International is a testing laboratory that currently evaluates HWT products. <http://www.nsf.org/>

1. enter into a Materials Transfer and Confidentiality Agreement with WHO;
2. pay WHO the fixed fee for the management of the Scheme and the cost for laboratory testing; and
3. send the required number of units of the product to the testing laboratory designated by WHO.

The Materials Transfer and Confidentiality Agreement will cover issues such as the manufacturer's agreement to adhere to the procedure of the Scheme (including as to the maintenance requirements), confidentiality of information, the provision of the devices for testing if the product is accepted for testing by WHO, the obligation to pay the fee and the testing costs, the ownership of the results by WHO, publication of the full testing reports, the manufacturer's commitment not to use the participation in the Scheme and the testing results for commercial or promotional purposes, etc.

It is recognized that some manufacturers in developing countries may not be able afford the full cost of testing, which on average will cost around 35,000 USD/device. Therefore, a subsidy may be provided to such manufacturers depending on availability of WHO funds. The criteria for determining whether a developing country manufacturer is eligible for the payment of the reduced fee will be developed by WHO with input from the Independent Advisory Committee (IAC). The criteria will take into account issues such as the location of the manufacturer headquarters, the manufacturer's market size, the health importance of the technology, plans for scaling-up, etc.

Consideration is being given to allowing the manufacturers whose products have been found to meet the WHO recommended criteria, to include the following sentence *discreetly* in material addressed to health professionals only: "This product has been tested as part of the WHO Evaluation Scheme for Household Water Treatment Technologies and was found to have a ["highly protective"], ["protective"] ["limited protection"] level of performance".

4.4 Evaluation of technology in designated testing laboratory

One of the testing laboratories designated by WHO will, subject to signature of a Technical Services Agreement with WHO, test the submitted device in accordance with the agreed procedure, using harmonized testing protocols and reporting templates. Each laboratory will be required: (i) to agree to the confidential treatment of the manufacturer's information and WHO ownership of the testing results; and (ii) to provide its reports to WHO no later than 90 days after receipt of the product documentation, product samples and funds to cover the testing costs.

Specific items for consideration in the protocols include appropriate microbiological challenge testing to enable categorization of devices into one of three performance tiers, reference pathogens, mimicking of a range of source water quality conditions, and testing products over the entire expected lifetime of use as indicated by the manufacturer.

WHO will have an appropriate agreement in place with each designating testing laboratory, to reflect the necessary arrangements, address confidentiality, ownership of the results by WHO, and other key issues of importance.

4.5 Review of testing results, publication and maintenance of evaluation status

All laboratory evaluation reports will be sent to WHO and submitted by WHO to the IAC. The IAC will review to reports and provide a recommendation to WHO on level of performance (i.e. “highly protective”, “protective” and “limited protection”) of each device.

Based on the recommendations of the IAC, WHO will, for those products that were found to meet the WHO recommended criteria, proceed to publish the full testing reports (subject to the protection of any confidential information of the manufacturer). A list of all tested devices and their performance level will be posted on the WHO website. The list will be accompanied by appropriate notes and disclaimers, regarding the audience of the list, use of the list, product inclusion and/or removal from the list, and other products not listed.

A listed product will not be reassessed, unless there is a change in circumstances which may affect the performance of the product (i.e. new manufacturing processes or materials, there is a complaint from the field, or fraud or omissions by the manufacturer becomes apparent. Manufacturers will be required to inform WHO annually whether there has been any change in circumstances which may affect the performance of the product. Reassessments will be conducted in the same way and subject to the same conditions as the original assessment, and the product list will, where appropriate be adjusted accordingly. Similarly, the full reassessment reports will (subject to the protection of confidential information) be published on the WHO website. WHO will remove a product from the list, if as a result of a reassessment, it appears that the product no longer complies with the WHO recommended criteria, or if the manufacturer fails to participate in the reassessment, or if the manufacturer fails to update WHO annually as required.

Finally, WHO may suspend a product from the list if new information becomes available to WHO which gives rise to serious concerns about the product’s ability to remove pathogens from drinking-water and reduce disease risk appropriate to the level designated (i.e. “highly protective”, “protective”, “limited protection”).

5. Capacity building and important considerations

As part of WHO’s mandate to strengthen the capacity of Member States to tackle global health problems, the Scheme will have a capacity building component. Capacity building will consist of three main activities: (1) informing/educating governments and HWT stakeholders about the Scheme and interpretation and use of results; (2) strengthening national capacity to test HWT technologies at the national level; (3) strengthening regulatory capacities regarding HWT technologies. These elements will be further developed with input from the IAC.

A number of activities are proposed to support these three activities. First, module training units will be developed by WHO in consultation with HWT and laboratory experts. These modules will be taught through webinars and the content made available online. Second, WHO will promote regional and inter-country laboratory exchange to train microbiologists in conducting evaluations and adapting the testing protocols to local conditions and resources. This work will be tied with wider efforts to improve the capacity of drinking water quality monitoring and surveillance that is being supported in part by the WHO/UNICEF Joint Monitoring Programme. Finally, regulatory capacities will be strengthened through regional workshops that bring

together all relevant ministries and institutional bodies. Where possible, these workshops will be held in conjunction with workshops of the UNICEF/WHO International Network on Household Water Treatment and Safe Storage on strengthening national policies and integration (WHO/UNICEF, 2011; 2012).

6. References

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Appendix 1: Terms of Reference for Independent Advisory Committee

The Independent Advisory Committee (IAC) will act as an advisory body to WHO on the International Evaluation Scheme for Household Water Treatment Technologies which will be managed by the Water, Sanitation, Hygiene and Health Unit (WSH) located within the Department of Health and the Environment (PHE).

Functions

The IAC shall have the following functions:

1. To develop and provide advice to WHO on:
 - criteria for the selection of the testing laboratories;
 - the evaluation and testing procedure;
 - harmonized testing protocols and reporting templates for testing results;
 - a template call for submissions; and
 - prioritization criteria for the categories of technologies to be evaluated and for the acceptance and handling of submissions.
2. Review and provide advice to WHO on the testing results of devices submitted to the Scheme for evaluation, including a recommendation on the level of performance (i.e. “highly protective”, “protective” and “interim”).
3. Generally advise WHO on the implementation and ongoing operation of the Scheme.
4. Provide advice and technical input to WHO on national capacity building activities, aimed at strengthening national capacity to test HWT technologies at the national level; and strengthening regulatory capacities regarding HWT technologies.

Composition and Responsibilities

1. The IAC shall have up to six members, who shall serve in their personal capacities. In the selection of the members, consideration will be given to attaining an adequate technical distribution of expertise, geographical representation and gender balance. IAC Members cannot be current WHO staff members nor can they participate in the Scheme itself.
2. Members of the IAC, including the Chairman, shall be selected and appointed by WHO. The Chairman's responsibilities include the following: chair the meetings of the IAC and liaise with the WHO Secretariat between meetings.

Selection criteria of IAC will include:

- At least 8 years of international experience in drinking-water quality, microbiology, water treatment technology and/or regulation.
- Demonstrated commitment to advancing public health goals through professional

- area of focus, publications, and involvement in professional associations.
 - Experience in strategic thinking and planning as demonstrated by participation in existing WHO Expert Groups, Advisory Committees or similar endeavours.
 - Excellent oral and written communication skills in English.
 - Willingness to devote at least 50 hours/year to IAC meetings and reviewing of testing reports and decisions.
- 3. Members of the IAC, including the Chairman, shall be appointed to serve for a period of three years after which they may be considered for reappointment by WHO for additional periods of three years each. Their appointment and/or designation as Chairman may be terminated at any time by WHO if WHO's interest so requires or as otherwise specified in this TOR or letters of appointment.
- 4. Representatives from inter-governmental organizations, as well as nongovernmental organizations in official relations with WHO, may be invited by WHO to participate in IAC meetings as observers. Upon invitation of the Chair, they may present the views and policies of their organizations and contribute to the discussions in the IAC. They will not participate in the process of adopting the final decisions or recommendations of the IAC.
- 5. Members must respect the impartiality and independence required of WHO. In performing their work, they may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of real, potential or apparent conflict of interest. To this end, proposed members/ members will be required to complete a declaration of interest form and their appointment, or continuation of their appointment, will be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

Operation

1. The IAC shall usually meet at least once each year. WHO shall provide any necessary scientific, technical and other support for the IAC. WHO may convene additional meetings, including through teleconferences and videoconferences, on an ad hoc basis as decided by WHO. The working language of the meetings will be English. Administration support for the IAC will be provided by WHO.
2. The cost of attending IAC meetings will be covered by WHO, on the basis of economy class travel via the shortest possible route and per diem entitlements/incidentals in accordance with the applicable WHO travel policy.
3. Members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the IAC. WHO may decide to appoint a member in replacement of that member.
4. Reports of each meeting will be submitted by the IAC to WHO. All

recommendations from the IAC are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the IAC. WHO also retains full control over the publication of the reports of the IAC, including whether or not to publish them.

5. Information and documentation to which members may gain access in performing IAC related activities will be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. IAC members shall not purport to speak on behalf of, or represent, the IAC or WHO to any third party. All proposed members will be required to sign an appropriate confidentiality undertaking and provisions on ownership.

Appendix 2: Criteria for designating testing laboratory

The following provides a list of criteria for selecting institutions as testing laboratories for the International WHO Evaluation Scheme for Household Water Treatment (HWT) Technologies.

1. Testing laboratories should preferably be institutions of which a department has been designated as a WHO Collaborating Centre (it being understood that the testing work would not be conducted by the institution as part of the WHO CC terms of reference or work plan).
2. The institution should be a not-for-profit, nationally or internationally recognized, ISO certified organization which conducts evaluations of household water treatment devices as part of its core activities. The institution should be independent of industry. Fees for the evaluation should be at cost. The institution should preferably be willing to waive the fees or set them at a lower level for those manufacturers of developing countries for whom the amount concerned represents an obstacle to participate in the Scheme
3. The institution should have established procedures in place to ensure that the trade names of the manufacturers and the brand names of the products are blinded to those who conduct the actual testing.
4. The head of the institution and the staff responsible for the testing activities should be required to disclose potential conflicts of interest, and the institution should have adequate mechanisms in place to address and manage conflicts to the satisfaction of WHO.
5. The institution should have a stable income from its core activities. The workload associated with the WHO HWT Evaluation Scheme should comprise of no more than 25% of the total workload of the institution.
6. The institution should agree to use and strictly adhere to the agreed procedure, the harmonized testing protocols and the reporting templates for testing results developed for the Scheme.
7. The institution should agree to report the testing results to WHO no later than 90 days after receipt of the product documentation, device samples and funds to cover the testing costs.
8. The institution should enter into a standard agreement for all participating testing laboratories, to reflect the necessary arrangements, address confidentiality, ownership of the results by WHO, etc.

Annex 2: Meeting Agenda

**Tuesday, 25 June
2013**

09h00-09h15	Welcome and introductions	Maria Neira, Director PHE
09h15-9h30	Meeting objectives and responsibilities of Independent Advisory Committee	Maggie Montgomery
09h30-10h00	Scheme overview and precedence <ul style="list-style-type: none">• Lessons learned from WHO Pesticide Evaluation Scheme• Development and approval	Rajpal Yadav, WHOPES Manager Maggie Montgomery Discussion moderator: Jennifer De France
10h00-10h30	Presentation of draft harmonized testing protocols	Nikki Beetsch, secondee WSH
10h30-10h45	Coffee break	
10h45-12h00	Discussion of test protocols	Discussion Moderator: Maggie Montgomery
12h00-13h00	Designated testing laboratories: quality control/assurance	Discussion Moderator: Nikki Beetsch, secondee WSH
13h00-14h00	Lunch	
14h00-15h30	Initial round of testing, including: <ul style="list-style-type: none">• Call for submissions• Minimum criteria for acceptance for testing• Prioritization of products• Reporting templates• Review of results by IAC• Timeline	Discussion Moderator: Maggie Montgomery
15h30-15h45	Coffee break	
15h45-16h45	Initial round of testing.... continued	
16h45-17h00	Wrap-up	Chair

Wednesday

26, June 2013

09h00-09h15	Summary of Day one	Chair
09h15-10h30	Interim category <ul style="list-style-type: none">• Consideration of “health impact” data• Communicating interim category• Additional testing required	Discussion Moderator: Maggie Montgomery
10h30-10h45	Coffee	
10h45-12h00	Consideration of products previously tested <ul style="list-style-type: none">• Criteria for considering existing tests• Additional testing required	Discussion moderator: Nikki Beetsch
12h00-13h00	Labelling and claims <ul style="list-style-type: none">• WHO recommendations on labelling• Responding to claims	Discussion moderator: Nikki Beetsch
13h00-14h00	Lunch	
14h00-15h00	Priority country capacity building activities <ul style="list-style-type: none">• Communications on Scheme• Strengthening regulation• Strengthening testing and linking with other water quality testing efforts	Discussion moderator: Jennifer De France
15h00-15h15	Coffee	
15h15-16h15	Next Steps <ul style="list-style-type: none">• Action items for WHO and IAC• Timeline for first round of testing• Next meeting	Discussion moderator: Bruce Gordon
16h15-16h30	Wrap up and close	Maggie Montgomery, WSH

Annex 3. List of participants

Name	Organization	Position
IAC		
Dr. Nicholas Ashbolt	University of Alberta School of Public Health Environmental Health Sciences	Professor
Dr. Joe Brown	London School of Hygiene and Tropical Medicine	Researcher
Dr. Charles Gerba	University of Arizona	Professor
Dr. Pawan Labhasetwar	National Environmental Engineering Research Institute	Principal Scientist
Ms Mien Ling Chong ¹	PUB, Singapore National Water Agency	Senior Engineer
WHO		
Ms. Nikki Beetsch	Water, Sanitation, Hygiene and Health	Seconded
Ms. Jennifer De France	Water, Sanitation, Hygiene and Health	Technical Officer
Mr. Bruce Gordon	Water, Sanitation, Hygiene and Health	Acting Coordinator
Dr Maggie Montgomery	Water, Sanitation, Hygiene and Health	Technical Officer
Dr Maria Neira	Public Health and the Environment	Director
Dr Rajpal Yadav	Control of Neglected Tropical Diseases	Scientist

¹Member of IAC, however was not able to participate in meeting.