World Health Organization

WHO/FWC/WSH/14.06

Procedure for Evaluation

WHO International Scheme to Evaluate Household Water Treatment Technologies

Geneva, Switzerland

Glossary

The definitions given below apply to the terms used in this Procedure. They may have different meanings in other contexts.

applicant
The entity who, by the deadline mentioned in an invitation issued by WHO, submits an expression of interest (EoI) to participate in this Procedure together with the required documentation on such product(s). Eligible applicants will be limited to manufacturers who have an established manufacturing process for market-ready household water treatment products.

designated testing laboratory
an internationally licensed laboratory that has been found to meet the criteria set forth in Appendix 1 and has been designated by WHO to conduct evaluations of household water treatment products for WHO according to a WHO harmonized protocol and the terms of this Procedure.

household water treatment product
A proprietary device or substance that is used in households or similar settings to remove or inactivate microbiological water contaminants that may pose health risks. Priority products for evaluation are low-cost, appropriate for low- or middle-income settings, generally "free standing" and which only treat enough water to serve a limited number of individuals each day, such as the members of a household or a community service setting, such as a school or health care facility.

household water treatment technology
The method or process by which household water treatment products remove or inactivate microbiological contaminants in drinking-water. Physical methods include boiling, heating (using fuel and solar), filtering, settling and ultraviolet (UV) radiation (solar or UV lamps). Chemical methods include coagulation–flocculation and precipitation, ion exchange, chemical disinfection with germicidal agents (primarily chlorine) and adsorption.

invitation for expressions of interest (EoI) or invitation
Invitation calling upon interested parties (e.g. manufacturers) to submit an expression of interest (EoI) to WHO by a specified deadline for the purpose of participating in the WHO Evaluation Scheme. Such an EoI should be accompanied by the required documentation on the product(s) in question.

Applicant
A company that produces and distributes (or has distributed) household water treatment products.

comprehensive protection: three-star (★★★) product
A household water treatment product that has been found to meet the top tier of the WHO recommended performance criteria and removes or inactivates at least 4 $\log_{10}$ of bacteria, 5 $\log_{10}$ of viruses and 4 $\log_{10}$ of protozoa.

comprehensive protection: two-star (★★) product
A household water treatment product that has been found to meet the middle tier of the WHO recommended performance criteria, and removes or inactivates at least 2 $\log_{10}$ of bacteria, 3 $\log_{10}$ of viruses and 2 $\log_{10}$ of protozoa.

targeted protection: one-star (★) product
A household water treatment product that has been found to meet the lower tier of the WHO recommended performance criteria, and meets *two* of the three targets of at least the second tier

of performance (at least 2 $\log_{10}$ of bacteria, 3 $\log_{10}$ of viruses or 2 $\log_{10}$ of protozoa). The target (i.e. bacteria, protozoa or viruses) for which the product fails will be specifically mentioned on the WHO list of evaluated products.

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1 Background

Household water treatment and safe storage (HWTS) is an important intervention to improve the safety of drinking-water and reduce diarrhoeal disease. HWTS provides an interim solution for populations without access to improved drinking-water sources, and where improved sources may be available, but not safe or reliable.

Increasingly, governments are addressing the use of household water treatment technologies (HWT) in national policies and health programmes as one means to address massive water quality challenges. Concurrently, manufacturers are continuing to develop and distribute HWT technologies throughout the world. All of these factors highlight the pressing need for objective and health-based evaluation of HWT to ensure that technologies which are distributed and used effectively remove pathogens to protect health.

Based on World Health Organization (WHO) global HWT microbiological performance recommendations[1], the International Scheme to Evaluate Household Water Treatment Technologies (the Scheme) was established in 2014. The Scheme guide WHO Member States and procuring United Nations (UN) agencies in the selection of HWT products.

The main objectives of the Scheme are to:

- promote and coordinate independent and consistent testing and evaluation of HWT 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 building the technical capacity of research and laboratory institutions for conducting complimentary assessments of HWT and, in general, applying recommendations of the WHO Guidelines for Drinking-water Quality at the national level[2].

HWT products that are found by WHO to meet WHO recommended performance criteria are included in a list published on the WHO website. Products on the list are classified in three ascending tiers based on their ability to remove viruses, bacteria and protozoa: ★ (one-star); ★★ (two-star); and ★★★ (three-star), as shown in Table 1.

Table 1: WHO performance criteria for household water treatment technologies

Performance classification	**Bacteria** (log_{10} reduction required)	**Viruses** (log_{10} reduction required)	**Protozoa** (log_{10} reduction required)	**Interpretation** (with correct and consistent use)
★★★	**≥ 4**	**≥ 5**	**≥ 4**	Comprehensive protection
★★	**≥ 2**	**≥ 3**	**≥ 2**	
★	Meets at least two-star (★★) criteria for two classes of pathogens			Targeted protection
–	Fails to meet criteria for one-star (★)			Little or no protection

Both three- and two-star products are classified as providing *Comprehensive protection* against all three microbial groups. One-star products are those that meet performance targets for only two of the three microbial groups and are classified as providing *Targeted protection*. The list is

[1] Evaluating household water treatment options: health-based targets and microbiological performance specifications. Geneva: World Health Organization; 2011 (http://www.who.int/water_sanitation_health/publications/household_water/en/)
[2] Guidelines for drinking-water quality, fourth edition. Incorporating the first addendum. Geneva: World Health Organization; 2017 (http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/)

principally intended for use by WHO Member States and UN agencies to assist in the procurement of HWT. Inclusion in the list does not imply any approval by WHO of the products in question (which is the sole prerogative of national authorities) and the list may not be used by manufacturers, suppliers or any other parties for commercial or promotional purposes.

2 Purpose and principles

The purpose of this WHO Procedure is to evaluate whether household water treatment (HWT) products meet the WHO performance criteria. The Procedure is based on the following principles:

- a general understanding of the production and quality control activities of the manufacturer through a review of submitted documentation;
- an assessment of HWT product data and information on safety, performance and user testing and assessment submitted by the manufacturer;
- an evaluation of the product by a WHO designated testing laboratories according to a WHO harmonized testing protocol and the terms of this procedure;
- an assessment of the results of the above mentioned evaluation to determine whether the product was found to achieve one of the three WHO recommended levels of performance: three-star; two-star; and one-star; and
- a possible re-assessment of the product and the handling of complaints from the field.

3 Steps of the Procedure

At regular intervals, and also taking into consideration pertinent input received from relevant United Nations agencies, WHO will publish an invitation to interested parties, requesting them to voluntarily participate in this procedure. By submitting an Expression of Interest (EoI), the applicant undertakes to share information with WHO on all relevant aspects of manufacture and safety, performance and user/field evaluations of the specified products along with planned manufacturing changes, if any. Interested applicants provide the necessary information to WHO by submitting a product dossier in the prescribed format, and other information as requested in the EoI.

WHO reviews the eligibility of the HWT products for testing based on information submitted by the applicants. Products which are deemed eligible for testing will be assigned by WHO for evaluation at one of the designated testing laboratories. A summary of all products accepted for evaluation will be provided on the WHO web site. Products will be tested based on the WHO harmonized test protocol which can be found on the WHO website at http://www.who.int/water_sanitation_health/water-quality/household/household-water-treatment-scheme-resources/en/.

At the conclusion of the testing and evaluation process (including an assessment of the testing results in consultation with an Independent Advisory Committee (IAC) appointed by WHO and a determination whether one of three levels of the WHO recommended performance criteria was found to have been met), WHO will report the results thereof to the applicant and publish a summary of the results on the WHO website. In addition, if the product(s) are found to meet one of the WHO recommended performance levels (‘three-star’, ‘two-star’ and ‘one-star’) WHO will list such product(s) with the applicable performance level on the WHO website. Throughout the screening and testing process, the WHO will seek input from the IAC. For details on the Terms of Reference of the IAC see Appendix 2.

4 Abbreviated Procedure

Those manufacturers whose products have been tested by one of the designated testing laboratories or an equivalent laboratory meeting the criteria outlined in Appendix 1, will be invited to include the testing data and results in product documentation submitted to WHO. Results from laboratories which WHO does not consider to meet all criteria in Appendix 1 will not be considered.

WHO will review such documentation and with advice from the IAC determine whether additional testing based on the Harmonized Testing Protocol and against the WHO recommended performance criteria is necessary. WHO will only consider results where the evaluation followed closely the Harmonized Testing Protocol, including evaluation of all three classes of pathogens (bacteria, viruses and protozoa), testing against two types of challenge water and testing the full expected lifetime of a product. As such, the applicant must also submit the detailed test plan which was used for the evaluation, in order for WHO to assess equivalency to the Harmonized Testing Protocol.

If the above conditions have been met and there is sufficient data for WHO to make a determination of performance level, such a determination will be made and, if WHO considers that one of the WHO recommended performance levels was found to have been achieved, the product will be listed on the WHO website. If the conditions have been met but WHO concludes that further testing is required, WHO will recommend that the product undergoes additional testing at one of the designated testing laboratories to allow for a determination of the performance level to be made.

This opportunity to include data for review is for manufacturers who have already generated data for some purpose other than the WHO Scheme and does not represent an alternate evaluation approach when strictly seeking evaluation to the WHO Scheme.

5 Invitation for Expression of Interest (EoI)

Invitation for evaluation to the WHO Scheme will be open and transparent, with all relevant parties invited to submit an EoI for qualifying HWT products. Information on invitation to submit will be published on the WHO web site and possibly shared as reminders through other media, such as the listserv of the WHO/UNICEF International Network on Household Water Treatment and Safe Storage. In situations of high public health concern as determined by WHO, direct invitation may be issued to relevant parties (known to and selected by WHO) to submit specified product dossiers for evaluation by WHO under this Procedure without publication of an invitation for EoI.

6 Data and information to be submitted

Interested parties are expected to submit documentation on qualifying HWT products as called for in the invitation for EoIs. Applicants should submit their product dossiers with the required information to WHO, before the deadline specified in the invitation. Instructions for the submission of the dossiers are included in the EoI. Eligibility will be limited to applicants who have an established manufacturing process for market-ready HWT products.

To ensure effective quality assurance for the manufacturing of the HWT product, it is expected that applicants present evidence of compliance with the principles and practices of quality management systems such as International Organization for Standardization (ISO) 9001:2015 Quality management systems (or an equivalent). The ISO quality management systems are

published by ISO and are available for purchase through national standards bodies.

In submitting an EoI for evaluation, the applicant should submit the completed submission form included in the invitation to WHO and if a date is specified, the submission should be on or before the specified date. This form will inter alia require applicants to submit information on: rights to the product, product details, a description of the treatment technology, use and maintenance, existing product data and approvals, any use and/or field trials and the product market strategy.

WHO will treat any information which has explicitly been marked "confidential" by the applicant as confidential and proprietary. In this connection, WHO shall (except as explicitly otherwise provided in this Procedure) take all reasonable measures to ensure that the information in question is not used for any purpose other than the evaluation and testing activities referred to in this Procedure and is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and restrictions on use as contained in the Confidentiality Agreement found in Appendix 3.

WHO shall not, however, be bound by any obligation of confidentiality or restriction on use to the extent it is clearly able to demonstrate that any part of such information:

a) was known to WHO prior to any disclosure by the applicant to WHO; or

b) was in the public domain at the time of disclosure by the applicant to WHO; or

c) becomes part of the public domain through no fault of WHO; or

d) becomes available to WHO from a third party not in breach of any legal obligations of confidentiality to the applicant.

If considered necessary or desirable by WHO (whether on its own accord or at the request of the applicant), and before the actual testing of the product starts, a discussion may be held between the applicant and WHO. This discussion should be scheduled as early as possible with a predefined agenda to address specified questions.

7 Screening of dossiers submitted

Each product dossier submitted by an applicant will be screened for completeness before being evaluated. Dossiers submitted for products which do not fall under the definition of "household water treatment" (see Glossary) and do not correspond to the specifications set out in the invitation will not be accepted for assessment. Similarly, WHO will not consider dossiers that are incomplete. The applicant will be informed that an incomplete dossier has been received and will be requested to complete the dossier within a specified time period.

In the event of non-compliance, the dossier may be rejected on grounds of incompleteness and returned to the applicant. Dossiers that are considered complete as the result of the screening will be retained by WHO for assessment.

After assessment, if the product is accepted for testing, the applicant will be informed of this, including the dossier reference number, by email. The applicant will be asked to respond within a specific time period if they are interested to proceed with testing. If affirmative, the applicant will be required to enter into the Confidentiality Agreement attached to this procedure as Appendix 3 and pay to WHO the assessed testing fee. See Section 13 for more details on cost.

8 Testing

Once a product has been accepted for testing and the Confidentiality Agreement has been signed,

WHO will assign a product for evaluation at one of the designated testing laboratories. A list of designated testing laboratories can be found on the WHO web site. Designated testing laboratories are selected in consultation with the IAC based on the criteria in Appendix 1.

Before testing begins, the designated testing laboratory will, based the WHO Harmonized Testing Protocol, develop a specific test plan for the product for approval by WHO. WHO will invite applicants to review and comment on the plan for WHO's consideration, before testing begins. Once the plan has been finalized, and payment for testing has been received by WHO from the applicant, the applicant will be required to send a specific number of product samples to the designated laboratory for testing. Subsequently, the designated testing laboratory will, under agreement with WHO, test the product in accordance with the terms of this procedure, using the WHO Harmonized Testing Protocol and reporting templates.

Each laboratory is inter alia required to: (i) agree to the confidential treatment of the applicant's information and WHO ownership of the testing results; and (ii) complete testing and provide its reports to WHO in principle no later than 120 days after receipt of the product documentation, product samples and finalization of the product-specific test-plan funds to cover the testing costs.

The testing will be based on the WHO guiding principles for evaluating HWT[3]. Specifically, this includes evaluating technologies against the three main classes of waterborne pathogens (bacteria, viruses and protozoa) at concentrations that allow for the demonstration of any of the three performance tiers. Testing reference pathogens are selected to most closely represent each class of pathogens and more generally the suite of pathogens found in faecally-contaminated waters globally. Refer to the Harmonized Testing Protocol available on the WHO website for the specific pathogens and the justification for their selection.

Another important aspect is that testing will be simulated to model actual field and use conditions. Thus, two types of challenge water will be used; the first representing high quality groundwater or rainwater and the second representing drinking-water with gross contamination of fecal matter. In addition, the experimental setup will model actual use conditions, where the product's manual or instruction for use will be followed by the laboratory technicians. Instructions may include any indicated product conditioning, mechanisms of the system to maintain or restore flow, flow control tools, conditioning, indicators of treatment complete, and indicators that water is unsuitable for the technology. Specifics can be found in the Harmonized Testing Protocol.

9 Reporting and communication of results

The designated testing laboratory will provide WHO with a report of the testing results, following the HWT Scheme reporting template, and providing summary of results and raw data in annexes.

Each such report will be submitted by WHO to the IAC for review and advice on which of the three HWT performance levels (i.e. 'three-star', 'two-star' or 'one-star) has been achieved for the product in question.

Following consideration of the IAC's recommendation, WHO will make a final determination on the performance level, and report the results of the testing to the applicant. In addition, WHO will (subject to the protection of any confidential information of the applicant) publish a summary of the results (including possible negative evaluation outcomes) on the WHO website. The summary will first be submitted to the applicant for comment, in order to ensure that it does not contain any confidential and proprietary information of the applicant.

[3] Evaluating household water treatment options: health-based targets and microbiological performance specifications. Geneva: World Health Organization; 2011 (http://www.who.int/water_sanitation_health/publications/household_water/en/)

In addition, WHO will list those products that have been found to meet one of the recommended performance levels on the WHO website. This list will be accompanied by the notes and disclaimers reflected in Appendix 4.

As WHO is responsible for the Scheme, the ownership of the testing results and reports lies with WHO. Thus, WHO shall be entitled to use and publish the reports subject always, however, to the protection of any confidential information of the applicant (as per the Confidentiality Agreement concluded by WHO with each applicant before testing). "Confidential information" in this context means:

- confidential intellectual property, know-how and trade secrets (including, e.g. formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks, patents, etc.); and
- commercial confidences (e.g. structures and development plans of a company).

Notwithstanding the foregoing, WHO reserves the right to share the full reports with the relevant authorities of any interested Member State of the Organization and interested United Nations agencies.

In the event of any disagreement between an applicant and WHO regarding the outcome of the testing, the Standard Operating Procedure (SOP) attached hereto as Appendix 5 will be followed. The final decision of any disagreement will ultimately rest with WHO.

10 Information material addressed to health/water professionals and government officials

Applicants whose products have been found to meet one of the WHO recommended performance criteria, may include the following sentence discreetly in technical material which is exclusively[4] addressed to health and water professionals as well as government officials: "This product has been tested as part of the WHO International Evaluation Scheme for Household Water Treatment Technologies and was found to have a ['Comprehensive protection: three-star'], ['Comprehensive protection: two-star''] ['Targeted protection (*microbial groups protective against*): one-star'] level of performance".

Except as explicitly provided above, applicants are not permitted to make any use of the WHO name and/or emblem, or use the outcome of the testing conducted as part of the Scheme for commercial or promotional purposes.

11 Maintenance of evaluation status

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, a complaint from the field, or fraud or omissions by the applicant becomes apparent). Applicants 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, a summary of the results of the reassessments (including possible negative evaluation outcomes) will (subject to the protection of confidential information) be published on the WHO

[4] The statement may not be included in or used on any other material, including but not limited to productlabelling, leaflet, instructions, manuals, etc.

website. WHO will remove a product from the list, if as a result of a reassessment, it appears that the product no longer meets one of the WHO recommended performance levels, or if the applicant fails to participate in the reassessment, or if the applicant 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.

12 Cost

In principle, the applicant will pay the full cost of testing according to the harmonized protocol. This cost may range from USD18 000-33 000 depending on the treatment technology. However, it is recognized that some applicants, especially those from developing countries, may not be able afford the full cost of testing. Subject to the availability of funds, WHO may in its sole discretion decide to waive part of the cost for such applicants. The criteria for determining whether an applicant is eligible for a reduced testing fee include: the size and capital resources of the applicant; applicant country of origin/location (with priority to those countries where safe drinking-water is least accessible); and the cost per litre of treated water delivered by the product.

Appendix 1. 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 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 Collaborating Centre 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 applicants 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 applicants 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, and other relevant requirements.

Appendix 2. Terms of Reference for the 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 is managed by the Water, Sanitation, Hygiene and Health Unit (WSH) located within the Department of Public Health, Social and Environmental Determinants of Health (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. 'Comprehensive protection: three-star', 'Comprehensive protection: two-star' or 'Targeted protection (*microbial groups protective against*): one-star'.
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: chairing the meetings of the IAC and liaising 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 3. Confidentiality agreement

WHO INTERNATIONAL SCHEME TO EVALUATE HOUSEHOLD WATER TREATMENT TECHNOLOGIES

STANDARD CONFIDENTIALITY AGREEMENT

between

....., having its principal offices at .....

.....(hereinafter referred to as “the Applicant”); and

the World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland, (hereinafter referred to as “WHO”).

The Applicant has developed (a) household water treatment technology(ies), known under the trademark(s) ……which (is) (are) further described in Annex 1 attached hereto (hereinafter referred to as “the Product (s)”) and information relating thereto (hereinafter referred as the “the Information”). The Applicant has submitted an application to WHO to have the Product(s) evaluated and tested in the WHO International Scheme to Evaluate Household Water Treatment Technologies (hereinafter refer to as "the Scheme").

Therefore, the Parties have agreed as follows:

1. The Applicant hereby confirms that it has taken good note of, agrees with and to the extent applicable, shall abide by, the provisions contained in the “Procedure for the WHO International Evaluation Scheme for Household Water Treatment Technologies" (hereinafter referred to as “the Procedure”).
2. The Applicant shall disclose and furnish to WHO the Information and sufficient quantities of the Product(s) in order to enable WHO to assess the Information and arrange for such evaluations of the Product(s), as WHO may determine are reasonably necessary to assess the performance of the Product(s) and (its)(their) suitability for use in treating contaminated drinking-water. At the conclusion of the testing and evaluation process, WHO will report the results thereof to the Applicant and publish a summary of the results on the WHO website. In addition, if the Product(s) are found to meet one of the WHO recommended performance levels as provided in the Procedure, WHO will list such Product(s) with the applicable performance level on the WHO website.
3. If and to the extent the Information has been marked by the Applicant as "Confidential", WHO shall treat such Information as confidential and proprietary for a period of 10 years after disclosure to it. In this connection, WHO shall (except as explicitly otherwise provided in the Procedure) take all reasonable measures to ensure that the Information in question is not used for any purpose other than the aforementioned evaluation and testing activities and is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and restrictions on use as contained in this Agreement.
4. WHO shall not be bound by any obligation of confidentiality or restriction on use to the extent it is clearly able to demonstrate that any part of the Information:
    a) was known to WHO prior to any disclosure by the Applicant to WHO; or

b) was in the public domain at the time of disclosure by the Applicant to WHO; or

c) becomes part of the public domain through no fault of WHO; or

d) becomes available to WHO from a third party not in breach of any legal obligations of confidentiality to the Applicant.

5. Except as otherwise provided in the Procedure and/or in this Agreement, each Party furthermore undertakes to abide by similar obligations of confidentiality and restrictions on use as contained in paragraphs 2 and 3 above with regard to the testing results and reports generated as a result of this Agreement (regardless of whether or not such results and reports have been marked as "confidential").

6. The provision of the Product(s), Information, testing results and reports hereunder shall not in itself be construed as conveying rights under any patents or other intellectual property which either Party may have or may hereafter obtain.

7. Subject to the protection of each Party's confidential information and the provisions of this paragraph 6, testing results generated under this Agreement may be published by either Party. In order to avoid prejudicing confidential information of the other Party, the submitting Party will transmit to the other Party for its review, the material intended to be published at least 20 (twenty) working days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of an objection by the other Party within that 60-day period concerning prejudice to its confidential information, and provided that all other conditions of this paragraph 6 have been met, the publication may proceed.

   In connection with the foregoing, it is understood and agreed that notwithstanding any other provisions in this Agreement, WHO shall be entitled to evaluate and publish the trial results, and to exclusively control this evaluation and the content of the aforesaid publication, provided that in order to avoid prejudice to the Applicant's confidential Information disclosed to WHO pursuant to paragraphs 1 and 2 above, WHO shall submit any proposed publication to the Applicant for review in accordance with the provisions of this paragraph 6. For the avoidance of any doubt, the Applicant shall only be entitled to object to a proposed publication if and to the extent it contains any confidential Information of the Applicant, and not on the grounds that the Applicant is not satisfied with the trial results and/or does not agree with WHO's evaluation thereof. Similarly, the Applicant shall not proceed to publish the testing results without having first submitted its proposed publication to WHO for review in accordance with the provisions of this paragraph 6, it being furthermore agreed that the Applicant's publication (or other public disclosure) shall be placed under embargo until WHO has been able to publish the testing results.

   All publications of the results of any evaluation and testing activities carried out under this Agreement shall include the following statement:

   "This investigation was carried out as part of the WHO International Scheme to Evaluate Household Water Treatment Technologies".

   Other than as provided hereinbefore, neither Party shall, in any statement or material of an advertising or promotional nature, refer to the relationship of the Parties under this Agreement or to the relationship of the other Party to the Product(s).

8. The Applicant shall provide the Information and at least 4 units of the Product(s) from different manufacturing batches to WHO, or the WHO designated testing laboratory, free of charge. Upon receipt of a written request to that effect from WHO, the Applicant shall furthermore

promptly pay or contribute towards the cost of the evaluation and testing process, as determined by WHO and otherwise in accordance with WHO's instructions. In the event that WHO and/or its designee(s) do not receive the Information, sufficient quantities of the Product(s) and/or the aforesaid payment of costs, WHO shall be under no obligation to arrange for the performance of any evaluation or testing activities in relation to the Product(s). Any balance of funds provided by the Applicant hereunder, and remaining unspent upon the conclusion of the testing and evaluation process shall be returned to the Applicant, unless otherwise agreed by the Parties.

9. After testing of the Product(s) in one of the designated testing laboratories, the units of the Product(s) made available for testing will not be returned to the Applicant. Rather, the designated testing laboratory will disinfect, destroy and dispose of the units and provide documentation that such measures have been taken to WHO.
10. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.
11. Nothing in or relating to this Agreement shall be construed as a waiver of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court or jurisdiction.

On behalf of WHO:	**On behalf of the Applicant:**
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

Appendix 4. Notes and disclaimers

WHO will list those products that have been found to meet one of the recommended performance levels on the WHO website with the following notes and disclaimers:

- This list is intended to guide WHO Member States and procuring UN Agencies in the selection of HWT.
- Inclusion in the list does not imply any approval by WHO of the products in question (which is the sole prerogative of national authorities).
- The list reflects the performance level which a product was found to meet at the time of testing.
- WHO cannot represent that the listed products will continue to meet the stated performance levels. WHO may suspend or remove products from the list based on information that may subsequently become available to it.
- The list is not an exhaustive list of HWT products but reflects those products that have been submitted to WHO for testing as part of the WHO International Scheme to Evaluate HWT. This list is updated regularly. HWT products (as identified in Invitations for Expressions of Interest (EOI) issued by WHO) are added to the list as and when (following the voluntary participation of relevant applicants in response to an Invitation for EOI) such products are tested pursuant to the HWT Evaluation Procedure and found to meet one of the WHO recommended performance levels.
- The fact that certain products and suppliers are not included in the list does not mean that if evaluated and tested, they would not be found to meet one of the three performance levels recommended by WHO.
- The list may not be used by applicants, suppliers or any other parties for commercial or promotional purposes.
- Inclusion of a product in the list and its indicated level of performance does not constitute an endorsement, or warranty of the fitness, by WHO of the product for a particular purpose, including in regard to its safety and/or efficacy in the treatment of water.
- WHO does not furthermore warrant or represent that:
    a. the list is complete or error free; and/or that
    b. the products listed have obtained regulatory approval for use in the treatment of water in every country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws.
- The improper handling of products may affect their level of performance.
- WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of or in connection with the procurement, distribution and use of any product included in the list.
- Any WHO Member State or UN organization intending to use this list of HWT products for procurement should perform other aspects of qualification prior to purchasing, such as ensuring financial stability and standing of the supplier, ability to supply the required quantities and other related aspects, including the registration status of the products they wish to procure.
- This list does not constitute any guarantee for the procurement of the products from the suppliers mentioned.

Appendix 5. Standard Operating Procedures for handling disputes and complaints

In the event that an applicant disagrees with the results of testing the following procedures will be followed:

1. WHO will ask the designated testing laboratory to demonstrate through laboratory documentation that the test plan was strictly followed
2. If WHO considers that the test plan was strictly followed, WHO in consultation with the Independent Advisory Committee (IAC) will review the entire set of raw data to ensure that the summary results are an accurate reflection of the data collected.
3. If WHO considers that the test plan was followed and confirms -in consultation with the AIC- that the summary results are an accurate reflection of the data collected, the reported results will remain unchanged and re-testing will not take place.
4. If the summary report is found by WHO not to accurately reflect the raw data, the report will be revised as appropriate and re-posted on the WHO web site.
5. If WHO considers that the specific test plan was not strictly followed, the designated testing laboratory will be asked to re-test the product at its own expense.
6. WHO's determination (in consultation with the IAC) as provided above will be final and binding, and not subject to any appeal.