WHO International Scheme to Evaluate Household Water Treatment Technologies

Round III

Expression of Interest Form

The Water, Sanitation, Hygiene and Health (WSH) Unit of the World Health Organization (WHO) invites manufacturers of point-of-use (POU)/household water treatment (HWT) products to participate in Round III of the WHO International Scheme to Evaluate Household Water Treatment Technologies (the Scheme).

The objective of the Scheme is to consistently and independently evaluate the microbial performance of HWT against WHO performance criteria, and in so doing, guide procuring United Nations (UN) agencies and Member States in HWT selection. The results of Round I have been published, and Round II results will be published at the end of July 2019. Preparations for Round III are currently underway.

Priority products for testing are low-cost, appropriate for developing country settings and generally "free standing" products which only treat enough water to serve a limited number of individuals each day. Further information on the minimum requirements is outlined in the Procedure for Evaluation (the Procedure)[1] .Only those products that are found by WHO to meet the minimum requirements for testing will be considered for evaluation under the Scheme. These requirements include completing, in its entirety, this Expression of Interest (EoI) form and submitting it to WHO. Any missing or unclear information or failure to submit by the deadline, are grounds for excluding a product for consideration in this round of testing. In addition, as described in the aforementioned Procedure, only products that meet the definition of HWT will be considered.

To participate, manufacturers are invited to submit Expressions of Interest (EoIs) for evaluation under the Scheme. Following an initial review of the EoI against the minimum requirements set forth in the Procedure, WHO may in its sole discretion accept or reject the product in question for testing under the Scheme, or request the manufacturer to clarify or revise one or more aspects (use instructions, more detailed description of the materials, etc.) and resubmit the EoI for WHO's consideration. If more eligible products are submitted for testing than can be accommodated by the Scheme, applications will be prioritized on a first come, first serve basis.

A list of the products accepted for evaluation under Round III will be posted on the WHO website. Manufacturers whose products will be accepted for testing under the Scheme will be required to enter into a Confidentiality Agreement with WHO as per the standard template which can be found in the Procedure on the WHO website listed above. Manufacturers will furthermore be required to pay for or contribute towards the cost of the evaluation. This requirement may partially be waived for manufacturers that cannot afford the full cost of testing. For more information in that respect, refer to the Procedure.

Eligible Manufacturers

The following lists the criteria for manufacturers that are eligible for submitting an EoI:

- Have an established manufacturing process for market-ready HWT products such that submission will be a representative of full production or limited production, in certain cases.

[1] Available at: https://www.who.int/water_sanitation_health/water-quality/household/hwt-scheme-procedure-2018_web.pdf?ua=1

- Provide evidence of manufacturing quality management, such as employing the principles of ISO 9001:2008 Quality management systems, which is published by the International Organization for Standardization (ISO) and available for purchase through national standards bodies[2].
- Use materials in their products for which the properties are well described in regards to their safety and composition or, for new materials, be able to provide evidence of safety of use in their submitted HWT product.
- Have developed robust and tested use instructions that are provided with the product as sold or distributed which will be used as the basis for developing specific test plans. Use instructions on product labels should be agreement with instructions indicated on other literature, including brochures, online resources etc. Where relevant, dosages and/or wait times should be clearly indicated, and the mechanism to deliver the dose should be provided.

General instructions

- Interested manufacturers are requested to complete this form and submit it together with any annexes to WHO. Completed and signed applications should be received by WHO by the deadline by email at hhwater@who.int and/or by mail addressed to:

  Coordinator
  Water, Sanitation, Hygiene and Health
  World Health Organization
  avenue Appia, 20
  1211 Geneva 27
  Switzerland

- To be considered, please make sure you answer all questions exhaustively. If not relevant to your technology, please state not applicable (NA).
- For those questions requesting pictures, drawings or evidence, please either provide references or attach the documents as separate attachments when submitting this form. If the files you wish to send exceed 5 MB, please notify us to provide you with an FTP site.
- Please be clear and concise in your answers.
- For question-specific instructions and exemplary answers please refer to the end of the questionnaire.

[2] The ISO standard can be accessed from the following link: (http://www.iso.org/iso/catalogue_detail?csnumber=46486)

A1: Contact information	
1. Manufacturer [*full name and address of manufacturing company*]	
2. Contact person	
3. Email address	
4. Contact telephone number *Please include country code*	
5. Company website	
6. Product website (if different)	
A2: Rights to product	
Please clarify whether the applicant/manufacturer is the owner of the product. If not, please clarify pursuant to what arrangement, the product is being manufactured (e.g. licensing agreement with rights holder, exclusive or non-exclusive, worldwide or not)	

B: Product details		
1. Brand name for product		
2. City and Country where product is manufactured		
3. Other cities/countries were the same product is manufactured		
4. Is the product commercially available?	☐Yes ☐No	If no, explain (*prototype, limited production, etc.)*:

5. Generic short description of technology (*see Annex 1 for example responses*)		
6. Are there procedures for quality assurance/quality control of manufacturing process? (*see Annex 1 for example responses*)	☐Yes ☐No	Briefly describe procedures:

C: Technology description
1. Description of product/technology ***Please provide a short description of your technology, including a brief technical explanation of the mechanisms by which your product removes contaminants from drinking-water.*** *If possible, please provide references and/or diagrams or other visuals to support your answer.*
Reference(s) title(s):
Please specify file name(s) for provided references/visuals:
2. Operation of technology *Please attach a manual or other instructions that explain how the product is used.*

Instructions included: ☐Yes ☐No	File name of the use-instruction:

3. Image of technology ***Please attach a picture illustrating the technology*** *(single image, high resolution (300 dpi))**.***		
File name of the picture:		
4. What is the capacity (lifetime) of the system (days, litres treated, etc.)?		
5. What is the daily production of the system? (L)		
6. What is the product's flow when new, if appropriate? (L/min.)		
7. Does the product's system flow slow (clog) with use?	☐Yes ☐No ☐N/A – disinfection batch treatment	
8. Does the product have an 'end of life' indicator?	☐Yes ☐ No ☐N/A	Indicator (*please describe*):
9. Does the product use a chemical disinfectant?	☐Yes ☐No	Disinfectant:
10. Does the product require other treatment for certain source waters? (*pre-filtration, etc.)?*	☐Yes ☐No	
11. What are the product's wetted components or ingredients?	Please complete form in Annex 2	
12. What energy source does the technology require?	☐None ☐Batteries ☐Power supply for recharging ☐Continuous power supply ☐Solar power ☐Other:	
13. Does the technology use software?	☐Yes ☐No	Describe:
14. Weight of the product (kg):		
15. What is the void volume of the system*? (mL or L). If a storage tank is part of the product, as sold, please specify its volume*		

16. Is the product portable?	☐Installed stationary ☐Mobile (on wheels, backpack, etc.) ☐Portable (hand-held, table-top, etc.)
17. Type of use:	☐Single-use ☐Reusable capital equipment

D: Use, maintenance and disposal		
1. Who is the intended user?		
2. Is training required in addition to the expected skill level of the intended user?	☐Yes ☐No	
3. Does the device require maintenance?	☐Yes	☐No
4. If maintenance is required, can it be done on-site?	☐Yes	☐No
5. If maintenance is required, please specify type/frequency (days/months/years)		
6. Under which water quality conditions can be product be used?	☐All ☐Must have non-turbid water ☐Other (specify)	

E: Product existing data and approvals
1. Technical evaluation of technology ***Please provide existing laboratory data on the microbial performance and/or safety of your technology. For technologies that include chemical components, such as disinfectants or coagulants/ flocculants, please provide laboratory or other justification to support the stated shelf life of the product.***
Reference(s):
If attachment included, please specify file name:
2. Regulatory status of technology ***Please provide information about the regulatory approval / certification of your technology in country of origin and/or countr(ies) of distribution.***

Reference(s):
If attachment included, please specify file name:
3. Field studies of technology ***Please provide information about any field studies your technology has undergone.*** *This could include health impact studies, user acceptability studies, etc., with the relevant attachments or online references*
Reference(s):
Please specify file name:

F: Market			
1. Date of initial commercialization (mm/yyyy)			
2. Annual production (number of units)			
3. Countries in which the technology is currently sold		4. Distributors	
5. Retail Price (USD)		6. List Price (USD)	
7. Shelf life of the product	Days Months Years		

G: Marketing strategy and Future challenges
Please provide information on your marketing strategy and foreseen challenges making your technology available and accessible to your intended user group, including scalability.

I hereby confirm that I am duly authorized to represent the manufacturer, and that the manufacturer holds all necessary rights to submit this application. I also confirm that the information provided is true and exhaustive.

Name:

Title:

Signature:	
Date (dd/mm/yyyy):	

Annex 1: Further instructions and example responses

B. Product details

5. Generic one-sentence description of technology: Please provide a generic descriptor for your technology. *Examples: "Gravity-fed filtration system"; "Batch treatment using flocculation followed by chlorination"*

6. Procedures for quality assurance/quality control:

Quality assurance

- How do you ensure consistency / quality in the materials / ingredients of the product?
- How do you ensure consistency in the manufacturing /assembly process?
- Is there a quality policy developed? e.g. ISO 9001
- Is there a specific guideline / best practice recommendations that you refer to?

Quality control

- Is there training and record keeping program for those involved in the manufacturing?
- Are there any visual inspections that are conducted? If so, what are the inspection criteria?
- Are there any verification tests that are conducted? e.g.:

  Disinfectants

  - What is the target concentration?
  - How is it verified?
  - How is the contact / retention time determined?

  UV

  - What is the target UV dose?
  - How do you ensure sufficient dose? e.g. EN 12975

  Filters

  - What is the target flow rate?
  - How do you ensure sufficient flow?

- Do you or any third-party agencies conduct microbial testing on the product samples? e.g. US EPA Guidelines, Lab Testing Results
- For the above quality control checks, what are the pass/fail criteria?
- What is the frequency for quality control checks? e.g. daily, every batch, certain percentage of units produced, random?
- What corrective measures are in place, in the event that the quality control criteria are not met? e.g. ISO 9001

C. Technology description

11. Provide the void volume of the system. Void volume is the amount of water the system holds when the system is wet.

F. Market

1. Commercialization: Please indicate the date of first commercialization, in which countries the product has received regulatory approval and is being sold.

J. Future challenges

Many potential obstacles can be encountered when bringing innovative technologies to new markets. The applicants are invited to identify challenges that they foresee to the successful future of their product, such as scalability to meet market demands.

H. Additional information

Use as needed.

Terms, Conditions and Disclaimers

WHO reserves the right not to select any application or to annul the solicitation process at any time, without thereby incurring any liability or any obligation to inform the applicants of the grounds for the WHO's action. WHO reserves the right, at any time during the solicitation process, to modify the scope of the Call. At any step in the evaluation process, WHO reserves the right to issue an amendment to the Call detailing the change to only those applicants who have not been officially eliminated at that point in time. Applications will be evaluated by WHO, with input from the Scheme Independent Advisory Committee.

Incomplete applications and applications submitted after the deadline will, in principle, be disregarded unless WHO, in its sole discretion, decides otherwise in respect of such incomplete or late application. WHO may request applicants to submit complementary or additional information as a condition for consideration. Any possible requests to submit complementary information and/or to submit a more detailed application, as well as any discussions ensuing therefrom, will be exploratory only, and do not mean that the applicant concerned will be selected.

Each applicant will be notified in writing by WHO (by e-mail) whether or not the submission has been selected. WHO reserves the right to freely decide on the selection of those products that will be accepted for testing under the Scheme, in WHO’s sole discretion, and without having to provide any justification to applicants whose products will not be selected. The selection process will not be subject to any claims or appeal. WHO will not in any circumstances reimburse any costs or expenses associated with the submission of an application (including possible complementary information and documentation), nor any costs associated with possible further discussions and/or the possible submission of a more detailed information. The submission and selection process set forth in this document will not be subject to claims for financial compensation of any kind whatsoever. Any information considered by interested entities as confidential must be clearly marked as "confidential".

Finally, it should be noted that although WHO welcomes collaboration with industry in the interest of promoting public health, WHO does not endorse any specific companies or branded products over others. In this regard, the WHO name and emblem may not be used for commercial or promotional purposes.

Annex 2: Wetted components / ingredient documentation

Materials in contact with drinking water must comply with WHO Guidelines for Drinking-water Quality (2017). For all products evaluated under the Scheme, documentation of the product components for systems and the ingredient and processing for chemical products is required. Forms for this documentation are included in this annex.

- **Chemical products:** The manufacturer must provide ingredient and processing information for chemical addition products. Changes to processing include, but are not limited to, changes in temperature, mixing and formulation rations.
- **Systems / devices:** The manufacturer must provide information on the performance impacting and wetted components for the product. Wetted components are those components in direct contact with the water to be treated or following treatment, such as o-rings, tubing or reservoirs. Performance impacting components, wetted or not wetted, include any component that that is integral to the product's performance, such as an indicator, lamp or pump. For systems that include that include a chemical, documentation of the components and the chemical used in the system is required.

Once a product has been evaluated under the Scheme, changes to components or processing from that tested shall require review by the WHO for consideration of additional testing in order to qualify changed components in a tested system.

SYSTEM WETTED AND PERFORMANCE IMPACTING COMPONENTS[1]				
Component	**Manufacturer**	**Model/Specifications**	**Material**	**WHO review** (*WHO to complete*)
Example: Gasket	Company XYZ	Model # 12345	FDA Silicone, 21 CFR.177.2600	

[1]Changes to components or processing from that tested shall require review by the WHO for consideration of additional testing to qualify changed components in a tested system

CHEMICAL PRODUCTS

PRODUCT FORMULATION AND PROCESSING[1]			
Ingredient	**Supplier**	**Processing**	**WHO review** (*WHO to complete*)
Processing description:			

[1]Changes to ingredients or processing from that tested shall require review by the WHO for consideration of additional testing to qualify changed components in a tested system.

MANUFACTURER STATEMENT:

I certify that the component and/or ingredient and processing information provided is accurate and complete.

On behalf of the Manufacturer:

Signature:

Name:

Title:

Date: