The Scheme:
Round II Evaluation Procedure: nuts and bolts

Nikki Beetsch, MS
Water, Sanitation, Hygiene and Health

World Health Organization

Round II Evaluation Procedure

Invitation for expression of interest

- Manufacturers to submit detailed information on product

Screening of dossiers

- WHO will review with input from the Independent Advisory Committee

Testing

- Specific plans based on harmonized test protocol, designated labs

  Abbreviated review

- Products that have already been *rigorously* tested

Testing Results and Reporting

- WHO with advice from IAC will determine level of performance
- Summary of ALL results posted on WHO website

Maintenance

- Manufacturers must update WHO on changes in product/manufacturing

World Health Organization

Quiz

- What are the 3 groups of pathogens that HWT technologies are evaluated against under the Scheme?

Key elements in evaluation of performance

Key elements:

- Test water phases: general (GTW) and challenge test water (CTW)
- Performance against the three main groups of pathogens which cause diarrhoeal disease in humans: bacteria; viruses; and protozoa
- Consideration for "lifetime"
- Disinfectant residuals in finished water
- Evaluation of microbial reduction/inactivation demonstrated against the log reduction criteria of the Scheme performance tiers

World Health Organization

Key elements in evaluation of performance

Evaluating household water treatment options: health-based targets and microbiological performance specifications **(WHO, 2011)**

- Applying the concept of tolerable burden of disease (acceptable risk) as set forth in the WHO Guidelines for Drinking-water Quality (GDWQ) (WHO, 2011).

- Using quantitative microbial risk models (GDWQ) and assuming background levels of reference pathogens in untreated water, reductions of pathogens were calculated to meet health-based targets.

- Three tiers of recommended performance (Tier 1, Tier 2 and Tier 3) were developed, denoting descending order of performance.

Key elements in evaluation of performance

Performance classification		Bacteria *Escherichia coli* (Log$_{10}$ reduction required)	Viruses MS-2 and phiX-174 (Log$_{10}$ reduction required)	Protozoa *Cryptosporidium parvum* (Log$_{10}$ reduction required)
Tier 1 (10^{-6} DALYs/ P/yr)	Comprehensive protection	≥ 4	≥ 5	≥ 4
Tier 2 (10^{-4} DALYs/ P/yr)		≥ 2	≥ 3	≥ 2
Tier 3 (*must be supported by health evidence*)	Targeted protection	Meets at least Tier 2 criteria for two classes of pathogens		

Quiz

- How many bacteria are in one gram of faeces?

Performance Classification

- **Tier 1/Tier 2** provide comprehensive protection against the three main groups of pathogens
  - Important where: (i) the burden of diarrhoeal disease is high due to several classes of pathogens; (ii) there is no information on the specific pathogens in drinking-water, and a prudent approach is to protect against all three classes; and (iii) there is a lack of safe faecal management and safe piped water supplies.

- **Tier 3** meet the targets for at least Tier 2 for two classes of pathogens.
  - In general, should be used in targeted situations where known pathogen of concern (e.g. in a cholera outbreak) or in combination with other products to ensure comprehensive protection.

Round II – Scheme reloaded

Harmonized Test Plan is a living document, subject to revisions that improve the evaluation and/or sustainability of the program.

- Goal: increase efficiency, decrease complexity and cost while maintaining rigor of the evaluation

- Balancing all considerations

- Answering "Does it work?"

Round II – Scheme reloaded

Goal: increase efficiency, decrease complexity and cost while maintaining rigor

- Round II (foreword of the revised harmonized protocol)
  - Fewer sample points – *all products*
  - Fewer microbial groups – *in certain situations*
  - Use of disinfectant concentration in the test waters – *for chlorine bleach*

- *Unless WHO deems otherwise, no additional evaluation of a product included in the Scheme under previous versions of the test plan will be required.*