



guardians of drinking water quality  
**DRINKING WATER INSPECTORATE**

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## **GUIDANCE ON SUBMISSIONS OF CLAIMS FOR REMOVAL OF ONE MICRON PARTICLES - MEMBRANE TREATMENT PROCESSES FOR *CRYPTOSPORIDIUM* REMOVAL**

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Department for Environment,  
Food and Rural Affairs

The Welsh Assembly Government  
Llywodraeth Cynulliad Cymru

## **GUIDANCE ON SUBMISSIONS OF CLAIMS FOR REMOVAL OF ONE MICRON PARTICLES - MEMBRANE TREATMENT PROCESSES FOR *CRYPTOSPORIDIUM* REMOVAL**

### **Background**

1. *Guidance on Assessing Risk from Cryptosporidium Oocysts in Treated Water Supplies* was developed by the Drinking Water Inspectorate (DWI) to support *The Water Supply (Water Quality) (Amendment) Regulations 1999* (Statutory Instrument 1524). The provisions of the 1999 regulations have now been incorporated in to the *Water Supply (Water Quality) Regulations 2000*. Copies of the Guidance and the Regulations are posted on the DWI website:

<http://www.dwi.gov.uk/regs/regulations.shtm>

2. Section 2.2 of the “Guidance On Assessing Risk From *Cryptosporidium* Oocysts In Treated Water Supplies To Satisfy The Water Supply (Water Quality) (Amendment) Regulations 1999 SI 1524 ” (<http://www.dwi.gov.uk/regs/crypto/legalindex.htm>) states that ‘any treatment works, in which all water passes through sufficient treatment plant capable of continuously removing or retaining particles greater than one micron diameter and where this process is subject to continuous monitoring and shutdown or turn out on failure, will not require continuous monitoring’.

3. This report contains guidance on the information to be provided by membrane suppliers in support of an application to DWI for listing of products as satisfying the criterion for removal of *Cryptosporidium*. Product information is not eligible for consideration unless the product is included in the *List of Approved Products and Processes*. A copy of this list , together with amendments and updates, is posted on the DWI website: <http://www.dwi.gov.uk/cpp/pagea.shtm>

4. The assessment criterion is that products must be capable of continuous removal (or retention) of particles of one micron diameter and greater from a representative feed water. The report deals only with size exclusion. Advice on membrane integrity issues and systems for monitoring membrane integrity is the subject of a separate DWI Information Letter 16/99 (<http://www.dwi.gov.uk/regs/infolett/1999/info1699.htm>). DWI will ensure that assessments are made independently of the commercial interests of manufacturers and suppliers of membrane and other filtration systems.

## Requests for assessment - initial submission

5. Requests for an assessment of product data should be addressed to Malcolm Morgan tel: +44 (0)20 7082 8041, E-mail: Malcolm.morgan@ defra.gsi.gov.uk. There are no specific requirements for format of submissions for assessment but suppliers must include:

- Contact details, including e-mail address, of the lead contact appointed by the supplier to co-ordinate the submission, and to deal with any correspondence over the assessment.
- A clear description and identification of the product to be assessed. This identification must appear on all parts of the information provided, to prevent ambiguity.
- Copies of claims made for the product that are relevant to the assessment.
- Relevant evidence about product performance in the water treatment process and the permitted operating conditions for the product when it is used in processes for drinking water treatment.

## Test data in support of submissions

6. DWI Information Letter 16/99 advised that test data on removal of oocysts of *Cryptosporidium* must indicate removal of **all** oocysts. In this respect, *Cryptosporidium* challenge tests are unlikely to provide definitive evidence of compliance with the assessment criterion. This follows from the limitations in the reproducibility and detection limit of available analytical techniques. However, suppliers may wish to provide results of *Cryptosporidium* challenge tests as supporting evidence.

7. Removal data on a range of alternative particles may be submitted as evidence for compliance with the test criterion e.g. bacteria, bacterial spores, viruses, phage particles and dissolved molecules or ions. The assessment will take account of possible differences in behaviour and size of the substitute particles and suppliers should provide a justification of why the behaviour of a particular particle is an adequate substitute for *Cryptosporidium*.

8. Similarly, particle removal tests are unlikely to provide definitive evidence of compliance with the assessment criterion, because of the uncertainties associated with ensuring zero breakthrough. However, suppliers may again wish to provide results of particle removal tests as supporting evidence. Tests performed with particles having a maximum diameter greater than one micron will be of limited value for the purposes of the assessment.

9. Imaging techniques such as electron micrography focus on the product rather than the process. The modal pore size of a membrane or filter may readily be estimated in this way. Evidence that the pores are generally of less than one micron in diameter is valuable confirmation of particle removal studies. However, by itself, evidence about the topography of the product is insufficient for a definitive assessment because (i) it addresses the assessment criterion indirectly, (ii) individual pores may be very much larger than the modal size, and (iii) parts of the filter surface may exhibit anomalous characteristics.

10. Gas or liquid permeation tests and mechanical resistance tests may be submitted as corroborating evidence. By themselves, they are insufficient because they are indirectly related to the particle removal process. The test principles and calculations used should be fully detailed.

### **Guidelines for experimental design**

11. It is recommended that product performance tests be specifically designed to evaluate compliance with the assessment criterion. If the tests were carried out with other applications in mind, this must be clearly stated in the description of the testing. Standard methods should be used wherever they are available and appropriate to the particles under consideration.

12. Test data may be obtained from experimental trials on production models or by monitoring the performance of working installations. Data from both types of studies will be advantageous. Data from working installations are particularly useful because they provide information on seasonal or episodic environmental variation, and human error. A complete operational record will generally be required.

13. Customer applications tests and product quality control tests may be submitted. The reason for carrying out such tests must be stated and the detailed procedure must be provided. Independent academic studies may provide comparative data on related products, but the provider's key contact must ensure that the product under assessment is clearly defined.

14. The results of tests carried out during product development are not eligible for consideration. Data must be obtained with identifiable products of known specification, using the commercial product under assessment. If it is necessary to use only a part of the commercial product for a particular test, or to study the commercial product integrated with other processes, this must be clearly stated at the head of each such test or study.

15. The Inspectorate will not consider tests results obtained in studies where two or more products are used in series. If it is necessary for water processed by the first unit to be treated by a second unit, then the product is not capable of complete removal of particles of the tested size and can not be assessed as meeting the assessment criterion.

16. The following points should be considered when designing performance tests:

- It will be necessary to reflect operational conditions thoroughly.
- Allowance must also be made for the recoveries, detection limits and linearity of analytical enumeration procedures, with appropriate control experiments.
- Results should be obtained for any start-up phase, shutdown phase or fluctuations during which water production might be allowed to continue, as well as for the steady state. This is particularly important if the retained material contributes to the filtration mechanism.
- It is desirable to include a control experiment for any dead volume contribution from, or adsorption to, apparatus that does not form part of the commercial product. Experiments in which the test apparatus is run without a barrier element in place are suitable

- A control experiment for adsorption to the barrier element of the commercial product would also be valuable. Adsorption may be allowed to occur for an extended interval in static mode (i.e. at zero flow rate) to determine whether it is a significant mechanism in particle removal.

## Reporting

17. Test reports on product performance in the water treatment process should include the following:

- Scientific procedures. Published scientific procedures should be submitted with the test data or referenced, and any modifications should be detailed. Other scientific procedures should be submitted in full, either as part of or with documents containing the test data.
- Raw data. Generally, all raw data will be required. However, if the volume of raw data exceeds ten pages, contact DWI for advice on the submission format.
- Interpretation, calculations and the conclusions drawn. Experimental design and statistical procedures may be referenced. Additionally, a rationale for the experimental design is valuable. DWI may commission statistical advice to assess the level of confidence in the reported data.

18. DWI will seek to identify whether the experimental basis for the submitted data is sufficiently rigorous. The information submitted should therefore cover the following details:

- Characterisation of particle size, type and number introduced to the process.
- Procedure for introducing particles before the process.
- Operational conditions covered.
- Procedure for recovering particles after the process.
- Enumeration of the recovered particles.
- Replication of all stages.
- Allocation of personnel, checking of results and quality assurance.
- Any operational difficulties. It may be necessary to repeat or redesign the tests if substantial difficulties are encountered.
- Any points at which parts of the product were replaced or modified.
- Whether the effects of backwashing, cleaning or maintenance were tested. The information available from in-process operational records may be less complete, but the same categories of information need to be addressed.

## Assessment process

19. DWI will examine and critically evaluate the information received against the assessment criterion, having regard to the relative significance of different types of information for this purpose. DWI will provide a written opinion as to whether or not the product meets the assessment criterion. Products receiving a favourable assessment will be included in the list "Approval of membrane and other filtration systems for *Cryptosporidium* removal". This list is posted on the DWI website:

<http://www.dwi.gov.uk/regs/crypto/approval.shtm>

## Conditions of listing

21. Listing is subject to the standard conditions of approval for all approved products in respect of: use in accordance with agreed Instructions for Use and approval of all changes to the product. Evidence about one product may be relevant to the assessment of a related product. For example, if the only intended difference is capacity. Nevertheless, the products should be clearly distinguished for the assessment. DWI will consider whether and to what extent cross-corroboration is appropriate.

These conditions of approval are as follows:

*That use is in accordance with an Instructions for Use document. Approval holders must provide water companies with copies of the Instructions for Use Document that was considered by the Committee<sup>1</sup> when approval was recommended.*

*That the approval of the Authorities<sup>2</sup> is obtained in respect of the following: any change in the formulation of the approved product, including change in source or identity of raw materials; any change in the manufacturing process, including location of manufacture; any change in designation of the approved product; and any change in name or ownership of the organisation holding the approval.*

1 The Committee on Products and Processes for use in Public Water Supplies

2 The Secretary of State for Environment, Food and Rural Affairs and the National Assembly for Wales.