

Advice Sheet 6

Approval of Membrane Filtration Systems & Associated Equipment

DOCUMENT CONTROL

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Version 2.4

March 2018

Preface

This series of advice sheets has been prepared by the Drinking Water Inspectorate (DWI) to provide guidance on the approval process for products for use in contact with water intended for human consumption.

The following advice sheets are currently available:

Advice Sheet	Title
1.	Overview of the Application Process
2.	Instructions for Use (IFU) Requirements
3.	Treatment Chemicals, Filter Media & Ion Exchange Resins
4.	Changes to Approved Products
5.	Products made from Recognised Grades of Materials
6.	Approval of Membrane Filtration Systems & Associated Equipment
7.	Construction Products for Water Retaining Structures
8.	Small Surface Area Products (Regulation 31(4)(b))
9.	Emergencies – Use of Equipment and Disinfectants
10.	Natural and Traditional Products
11.	Product Re-approval Process

Availability

Copies of the most up-to-date versions of these advice sheets can be freely downloaded from the [DWI website](#).

Application Forms

A series of product type related applications forms are available from the [DWI website](#).

Laboratory Test Protocols

A series of product type related laboratory test procedures are available from the [DWI website](#).

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Glossary

The Regulations

The following regulations apply to the approval of substances and products used in the provision of public water supplies within the United Kingdom:

- a) England - regulation 31 of [The Water Supply \(Water Quality\) Regulations 2016](#) (Statutory Instruments 2016 No 614).
- b) Wales – regulation 31 of [The Water Supply \(Water Quality\) Regulations 2010](#) (Welsh Statutory Instrument 2010 No 994 (W.99) - and [Amendment Regulations 2016](#) (No. 410 (W. 129))
- c) Scotland – regulation 33 of [The Public Water Supplies \(Scotland\) Regulations 2014](#)
- d) Northern Ireland – regulation 30 of [The Water Supply \(Water Quality\) \(Amendment\) Regulations \(Northern Ireland\) 2009](#) (Statutory Rules of Northern Ireland 2009 No.246)

Where reference is required to specific regulatory requirements, these are given in footnotes.

The Authorities

Under the relevant regulations water suppliers shall not apply or introduce any substance or product into public water supplies unless the requirements of the relevant regulations are met. One of these requirements is that the substance or product has been **approved** by either the Secretary of State for the Environment Food and Rural Affairs (England), the Welsh Ministers (Wales), the Northern Ireland Assembly (Northern Ireland) or the Scottish Ministers (Scotland); collectively referred to as “the Authorities”.

The List

Under the relevant regulations lists of all the substances and products approved or refused, and of all approvals revoked or modified are published at least once a year:

- England and Wales:* this list is regularly updated by DWI throughout the year, and includes details of changes to approved products and additions to the List; the list (the [List of Products for use in Public Water supply in the United Kingdom](#)) is posted on the DWI website. Reference to “the List” throughout this publication refers to the most up-to-date version available from the website.
- Scotland:* a list is published annually by the Scottish Government on their [website](#).
- Northern Ireland:* in due course the Department for Regional Development (Northern Ireland) will also publish a list.

The Approval of a Product

Approval is based upon consideration as to whether the use of a substance or product will adversely affect the quality of the water supplied, or cause a risk to the health of consumers; no consideration is given to fitness for purpose and approval by the Authorities must not be taken as a favourable assessment of the performance or merits of any substance or product. It is the responsibility of the end user to ensure fitness for purpose.

The approval process for general products used with water intended for human consumption is set out in [Advice Sheet 1](#). Relevant deviations from this process are set out in the appropriate Advice Sheets.

Water Suppliers

These include water undertakers, inset appointees, and water supply licensees; see The Water Act 2003 (Consequential and Supplementary Provisions) Regulations 2005.

1. Introduction

Approval of membrane filtration systems varies from the approval process described in the other Advice Sheets, and so this Advice Sheet relates primarily to membrane filtration systems.

2. Initial Approval

2.1 Application

Applications should be made in the normal way, as described in [Advice Sheet 1](#), using the appropriate Application Form.

BS 6920 testing (or European equivalent testing) and full formulation details must be provided for each component that is in contact with water.

Information on the requirements of the Instructions for Use document can be found in [Advice Sheet 2](#). If a preservative is used with the membrane, test data showing the effectiveness of the rinsing procedure (the “die-away curve”) should be included with the application if available. This rinsing procedure should also be described in the IFU.

If a cleaning regime is specified in the IFU, test data showing the effect of the cleaning procedure on the product water (including the concentrations of any cleaning compounds detected in the product water after cleaning) should be included with the application if available.

Reports submitted to the DWI with the application regarding preservative flushing or cleaning procedures must contain:

- A detailed description of how the test was performed, e.g. temperature, free-chlorine concentration, etc.
- Chain of custody of any test samples and test waters
- A summary of the analytical method used
- The detection limits (normally required to be $\leq 10 \mu\text{g/l}$), AQC data and accreditation status for the chosen analytical method
- Test results and appropriate graphs

2.2 Testing

Leachates prepared on the complete systems in accordance with BS EN 12873-4 shall be used to:

1. Verify the “die-away curve”, if required.
2. Determine the presence and concentration of parameters requested by the DWI.
3. Verify the effects of cleaning procedures on the product water, if required.

The test rigs needed to prepare leachates can be large. In cases where it is not practical to prepare leachates on the premises of test laboratories care and planning needs to be undertaken

to ensure the security of the rigs used for leachate preparation. In these cases the security of the test rig must be fully under the control of the test laboratory, the test rig must be physically isolated from access by any other people and the test laboratory must be present whenever access to the test rig is required. To achieve this degree of security the following is normally required:

- This work is undertaken in a bonded area to which only the test laboratory has access.
- The test laboratory shall take full responsibility for the chain of custody of all test leachates during transport from the test rig to the test laboratory.

The applicant and the test laboratory should submit a draft test protocol, including details of where the leachates will be prepared, what security measures will be put in place (including locks and tamper-proof security seals), and how, and by whom, the test leachates will be transferred to the test laboratory for subsequent analysis. The protocol should include all commissioning, disinfection and rinsing processes, together with information concerning all monitoring and control of test conditions, including the temperature of test water throughout the period of leachate preparation.

If there is any breakdown in security, for whatever reason, this will invalidate the leachate preparation, and the tests will have to be re-started with fresh test units.

3. Changes to Materials or Components

The process for making changes to products is described in [Advice Sheet 3](#). The following is additional information specific to membrane systems.

The following approach taken to changes will depend on the role of the component:

1. small surface area components which were not part of the filtration system, e.g. connectors, valves, etc. Disclosure of the full formulation and conformity with odour and flavour and growth of aquatic microorganisms tests (BS 6920) of the new material or component.
2. components with greater contact with water e.g. pressure vessels, membrane support materials (but not the active coating). Disclosure of the full formulation and full testing to the requirements of BS6920 (Parts 1 and 2) plus TOC and GC-MS analysis of leachates using a static soak to prepare leachates (BS EN 12873-1).
3. active membrane components, full testing to the requirements of BS6920 (Parts 1 and 2) plus TOC and GC-MS analysis of leachates, together with analysis of any specific determinands requested by DWI, using a re-circulating leachate preparation procedure (BS EN 12873-4).