



guardians of drinking water quality

**APPROVAL OF PRODUCTS  
FOR  
USE WITH DRINKING WATER**

## **Advice Sheet 2**

# **Instructions for Use (IFU) Requirements**

**DOCUMENT CONTROL**

The only controlled version of this document can be accessed on the [DWI Website](#). Printed copies of this document, together with electronic copies held on local computers and other storage devices are uncontrolled.

**Version 5.3**

**February 2017**

## 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
<b>2.</b>	<b>Instructions for Use (IFU) Requirements</b>
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](#).

### Contact

For further information or help please contact:

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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

*Products are considered, assessed and tested on the basis of your IFU and any final approval given makes it a legal requirement to adhere to the IFU.*

The Instructions for Use (IFU) document is an integral part of the approval. The test requirements specified by the DWI for assessment of the products potential effects on water quality will be based on the IFU document. This ensures that the testing carried out mirrors as closely as possible the actual conditions under which the product will be used.

After approval is given the IFU ensures that the end user uses the product in a way that minimises the potential for the product to adversely affect water quality. Failure by the end user to follow the IFU document invalidates the approval and could result in prosecution.

## 2. Content of the IFU

The IFU should be comprehensive, up to date and solely describe use in the supply of water intended for human consumption.

### 2.1. General Requirements

The content of the IFU will vary depending upon the nature of the product and the mode of use. As a minimum, however, the document must:

- be a formal, comprehensive self-contained document which is identified by title, issue number, date of issue and contact details with each page numbered sequentially
- be product specific, but can cover a range of similar products of different dimensions made from the same materials and components
- relate specifically to the use of the product for water intended for human consumption
- indicate the scope of use
- specify the conditions of use which will apply when the product is approved
- use metric units; alternative units can be provided within brackets after the metric unit
- include the accepted UK use of a period for a decimal point and a comma or space as a separator for thousands, e.g. 1,234.5
- include details of any special storage conditions
- describe how the product will be installed
- provide details of routine checks on performance in operation, if applicable

## 2.2. Site Applied Materials

In addition, for site applied products (including *in-situ* linings), it must:

- indicate methods of surface preparation
- describe the packaging and identification of multi-component parts, including colour of each part and the finished lining/coating
- include the following details of the application process for each layer (including primers and undercoats)
  - the mixing process, including mixing ratios, how its undertaken and pot life
  - method of application (for example brush or spray)
  - minimum temperature of application and any environmental controls and humidity restrictions
- give details of curing conditions including
  - cure period
  - temperature
  - relative humidity (if applicable)
  - cure curves may also be included
- include details of any known incompatibilities with potential substrates onto which the product could be applied
- include details of how repairs can be undertaken
- In-situ applied linings for water mains must be applied in accordance with the requirements of the Water Industry Information and Guidance Note IGN 4-02-02 "Code of Practice: In-situ resin lining of water mains" and the Water Industry Specification WIS 4-02-01 "Operational Requirements: In situ resin lining of water mains" both available from Water UK. These documents refer to specific information that has to be included in the product Instructions for Use.

## 2.3. Pipes

In addition the IFU should include:

- physical dimensions of the product range (using the same materials and methods of manufacture) for which approval is sought
- jointing including mechanical, solvent welding and heat welding instructions as appropriate or reference to Water Industry Specification WIS 4-32-08 "Fusion jointing of polyethylene pressure pipeline systems using PE80 and PE100 materials"
- for lined pipe, instructions for repair of small defects prior to installation, and instructions for making good at joints and following future repairs

## 2.4. Tanks, Reservoirs and Pressure Vessels

In addition the IFU should include:

- physical dimensions and volumes of the product range (using the same materials and methods of manufacture) for which approval is sought
- installation and assembly instructions including details of all ancillary equipment and components, e.g.:
  - ladders, roof stays, access points, jointing and sealing compounds used in assembly

## 2.5. Treatment Chemicals (including disinfectants and cleaning agents)

In addition the IFU should include:

- any preparation prior to usage (e.g. dilution) and details of all commissioning procedures undertaken by the end user
- method, control and point of dosing
- the maximum and maintenance dosage rate
- test methods to determine chemical and dose strength
- routine monitoring of dose strength
- storage conditions and shelf life
- procedures to be adopted before the treated apparatus is returned to service (e.g. flushing) if appropriate
- any restrictions on the use of the product which ensure that water supply does not become contaminated with the product

## 2.6. Adsorbents, Filter Media and Ion Exchange Resins

In addition the IFU should include:

- type of resin
- details of media size, depth, capacity etc.
- preparation of the filter bed
- bed volume
- bed conditioning procedures (flow rates, pH stabilization)
- procedures for regeneration of the product, if applicable
- expected life-in-use
- storage conditions

## 2.7. Electrochemical Generation Products

In addition the IFU should include:

- all operational details, including full details of chemicals used
- expected life of the generated product

## 2.8. Membrane Systems

It is not necessary for applicants to provide the DWI with a complete set of operating manuals for a filtration system. However, it may be appropriate to include abstracts from these manuals together with other information that will enable the end user to quickly assemble the product and operate it effectively. The IFU should contain:

- explanation of the water type for which the unit has been designed, e.g. brackish, partially treated etc., and the suitability of the system for use with chlorinated water
- details of the preserving system(s) used
- the commissioning instructions should include:
  - die-away curves which demonstrate the volume of water and rinsing times required to completely remove any traces of preserving fluids from the unit
  - a means of verifying under plant conditions that removal of these fluids has been effectively carried out

- typical, minimum and maximum flow rates
- typical volume of water treated before the membrane is taken out of service for cleaning
- cleaning instructions should include (as appropriate):
  - details explaining when cleaning is required
  - information about any cleaning chemicals used
  - the procedures for removing cleaning agents before the unit is put back into supply
  - the volume of raw or treated water to be used in backwashing and cleaning
  - die-away curves for the removal of cleaning/disinfecting agents
  - a means of verifying that under plant conditions removal of these agents has been effectively carried out
- details of any on-line dosing of chemicals (e.g. descalants) and evidence of their removal
- typical life before replacement is needed

## 2.9. Emergency Equipment

A wide range of product types are covered under this category. Only general guidance on requirements for the IFU can be given therefore; further detailed advice can be obtained from the Regulation 31 enquiries team. However, the following should be considered:

- proposed use
- any critical storage requirements, to prevent contamination
- assessment of status before deployment, including state of packaging and any tamperproof seals etc
- pre-cleaning and sterilisation before use
- details of any assessment or test requirements before use, e.g. odour and flavour assessment, microbiological sampling
- how the equipment will be used, including details of all associated ancillary equipment required, whether provided with the product, or obtained locally, any specific labelling requirements, and length of service before redisinfection is necessary
- how the product will be assembled, if appropriate, and tested before use
- appropriate reference to regulation 6(3) of the Water Supply (Water Quality) Regulations 2016, and how the requirements of this will be met in use.
- One-use products must specify that the product must not be re-used
- Multi-use products must include relevant post-use cleaning and storage requirements



### 3. Structure of the IFU

The text of the IFU should be set out in headed sections that reflect the sequence the user needs to follow in order to understand the proposed use of the product, its introduction into use, continuing operation and safeguards for drinking water quality. You are encouraged to set out the guidance in a logical sequence making use of headings and sub-headings, and using schematic drawings and photographs when these will help the user.

An indicative structure is given below that will enable you to include all the elements of this guidance, as appropriate for the product. It is emphasised that this guidance cannot be prescriptive due to the diversity of products and their uses.

**Description of the Product**

Describe what the product is, including physical and chemical parameters.

**Description of Product Use**

Describe what the product is used for, including the scope and restrictions on use by drinking water suppliers.

**Product Application**

Describe how the product is used. It will probably help the user if this section is set out with sub-sections which may include product packaging and delivery, assembly, component mixing, application methods, curing etc.

If the product can only be applied or installed by specific contractors, this requirement will be included as a condition of approval. If the product application requires staff to work in restricted areas they should have a National Water Hygiene Card.

**Commissioning and Preparing a Product for Use, Including Disinfection**

This will include instructions on any cleaning, flushing and disinfection routines, together with any checks and tests to ensure the product is fit to be put into use. As chlorine is commonly used for disinfection it is important that you describe any conditions on the maximum allowable exposure of the product to chlorine both by concentration and contact time.

**Operational Routines**

Any routine monitoring, performance checks and routine maintenance should be described. A detailed maintenance manual is not required but attention should be drawn to routine measures that need to be taken to ensure the satisfactory and effective use of the product. Procedures for the stopping and re-starting of product use should be included.

**Storage**

Conditions for product storage together with its shelf life should be described.

## 4. Submission of the IFU

It is a requirement that the Instructions for Use document(s) is submitted electronically to the Inspectorate in MS Word or “rich text” format.

E-mail: [reg31.enquiries@defra.gov.uk](mailto:reg31.enquiries@defra.gov.uk)

### 4.1. Delays in Processing Applications

Poorly written or badly presented IFU documents are the major causes of delays in processing applications. Normally a product will not be considered by DWI for approval under the relevant regulations without a satisfactory IFU, and usually DWI will not agree to the release of any appropriate test requirements until they are completely satisfied with the IFU.

## 5. Useful Reference Documents

Civil Engineering Specification for the Water Industry, published by WRc plc on behalf of UK Water Industry Research Ltd.

Principles of Water Supply Hygiene & Technical Guidance Notes, Published by Water UK and available from, <http://www.water.org.uk>

WIS and IGNs

Water Industry Information and Guidance Note IGN 4-02-02 "Code of Practice: In-situ resin lining of water mains"

Water Industry Specification WIS 4-02-01 "Operational Requirements: In situ resin lining of water mains"

Water Industry Specification WIS 4-32-08 "Fusion jointing of polyethylene pressure pipeline systems using PE80 and PE100 materials"