



guardians of drinking water quality

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

Advice Sheet 11

Product Re-approval Process

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.

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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 in Water Collection, Treatment and Distribution Systems
8.	Products Permitted to be used under Regulation 31(4)(b) - Small Surface Area Exposure
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

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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 products is granted on the basis of the information provided to the Drinking Water Inspectorate (DWI) by the applicant and data from any testing undertaken. In order to provide assurances that products included in the list have not changed and so continue to be suitable for contact with drinking water, all products are now subject to a re-approval process five years after the initial approval date.

2. Re-Approval Process

Applications for product re-approval should be submitted to DWI before the expiry date of the product. If the re-approval application is submitted after the expiry date then the product will be removed from the next version of the Secretary of States' list until such time the re-approval has been granted.

In all cases DWI will endeavour to contact the product holder by letter to inform them of the requirement to submit the relevant information for the process to begin.

In order to apply for a product re-approval the following information will need to be submitted:

- a. A completed re-approval application form (forms can be downloaded from the Inspectorate's website at <http://www.dwi.gov.uk/drinking-water-products/advice-and-approval/index.htm>);
- b. Full formulation and relevant associated Material Safety Data Sheets (MSDSs) for each component. You may need to use this [link](#) to request that your suppliers provide this information directly to DWI.
- c. Details of the quality management system for the manufacture and supplier of the product;
- d. The current Instructions for Use (IFU) document.
- e. A statement from the company indicating that no changes to either the formulation, the place of manufacture have taken place or, if changes have been made, an outline of the changes that are being requested to take place during the re-approval of the product
- f. Copy of the current approval letter

2.1 Changes Requests made to Products during the Re-approval Process

Whilst required changes made to the product during its approval period must be notified to the DWI through a Change Application and before the change is implemented, the DWI may accept a change application included within a product re-approval application. However any changes submitted as part of the re-approval process may lead to testing and may delay the re-approval of the product.

Note: Changes made to a product without notification to DWI will break the conditions of the approval, and if picked up through the re-approval process, could result in the immediate de-listing of the product and any water undertaker using the product could be in breach of the requirements set out in the relevant regulations.

2.2 Change Requests made within 6 months of the Re-approval Expiry Date

If a Change Application is received by the DWI within the 6 month period before the products expiry date then the DWI will include the products re-approval application within this review. This may result in additional information being submitted in order to satisfy the information required above. In each case the DWI will contact the product holder to inform them of this process.

3. Charges

Where no changes have been made then a charge of £350 is required to assess the application and renew each product approval.

However, further charges may be incurred if significant changes have been made to the product, or place of manufacture, since the approval was granted without prior notification to DWI, this may result in the temporary de-listing of the product until the changes have been fully assessed and accepted.

4. Timescale

The time taken to assess the information and issue a new approval letter will be dependent upon:

- the completeness and quality of the supporting information provided
- whether any changes have been made to the product and/or the place of manufacture
- the need for any additional testing
- clearance of payment

5. Expiry Dates of Approval

On receipt of the new approval letter the product will be valid for a further 5 years.

For those products where the re-approval information is submitted and processed in advance of the products expiry date then the 5 year period will still begin from the original expiry date

For those products where the expiry date lapses whilst the re-approval is still being reviewed then the product will be removed from the list and re-added once re-approval has been granted.

If DWI is not contacted by a product approval holder about their re-approval by the products expiry date, the product will be removed from the Secretary of States' list published immediately after the expiry date has passed and added to Annex 1. Those products will then be subject to the full approval process if the approval holder wants to add the product to the list at a future date.