guardians of drinking water quality

APPROVAL OF PRODUCTS FOR USE WITH DRINKING WATER

Advice Sheet 4

Changes to Approved Products

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
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:

Regulation 31 Enquiries,

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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. It is a condition of the products approval that any changes to the product require authorisation from DWI in advance. These changes can include:

- the name or designation of the approved product
- the name of the approval holder
- the site of manufacture
- the nature and composition of the product
- the nature and source of ingredients, and where appropriate their composition
- the manufacturing process
- the quality management system for the manufacture and supply of the product
- the method of use or application
- the Instructions for Use

Any change, associated to the above, to an approved product must be notified in writing or in electronic format to DWI's Regulation 31 team as soon as possible **and certainly BEFORE the proposed change is implemented,** so that an assessment can be made. A change application form is available on the DWI website at: http://www.dwi.gov.uk/drinking-water-products/advice-and-approval/index.htm

If you fail to notify the DWI of a proposed change to an approved product before the change is implemented you will break the conditions of the approval which could result in de-listing of the product and any water undertaker using the product could be in breach of the requirements set out in the Authorities regulations.

2. Administrative Changes

Administrative changes to the details given on the List of Approved Products and the Approval Letter but not affecting the product must still be notified to DWI. These changes can include:

- the name or designation of the approved product
- the name of the approval holder
- change to the contact address or email (but not to the manufacturing site)
- rebadging of the product by another supplier (with agreement of the approval holder)

The following information will be required by DWI, in writing:

- a completed change request application form
- documentary evidence of the company name change (where applicable)
- a copy of the current approval letter
- a revised copy of the Instructions for Use (IFU) document including the changes
- conformation that no other changes are being made

In most cases these types of changes will not incur a charge but DWI reserves the right to charge £350 where a change involves a significant amount of work, for example, significant changes to the IFU or changes affecting multiple products.

Where a product is to be rebadged a completed Application Form will also be required from the new supplier along with written agreement of the original approval holder. The revised IFU must conform to the current requirements for an IFU set out in Advice Sheet 2.

3. Change to the Site of Manufacture

Where manufacture of a product is going to be relocated to a different site or an additional site is to be used then this should be notified to DWI in writing or in electronic format before the change takes place confirming continuity of supply of the approved product and giving the following additional information:

- a completed change request application form
- full details of the proposed new manufacturing site, including the full postal address
- date of the proposed move
- details of any changes in the sources of the ingredients used in the manufacture of the product
- full formulation details of the product
- details of any changes in the manufacturing process
- details of the quality management system for the new site
- confirmation of whether changes in the IFU will be required
- a copy of your current approval letter
- payment of £350

Audit testing of the product manufactured on the new site may be required. Once agreed, DWI will confirm the status of the new site in writing or in electronic format.

4. Changes to the Product

4.1. Required Information

For any notification regarding a change to the raw materials, components, method of manufacture or to the quality management system, then the following information must be submitted to DWI in writing or in electronic format:

- a completed change request application form
- the type of change being proposed, together with the reason(s) for the change
- the full product formulation originally approved and a copy of your current approval letter
- the full revised formulation highlighting ALL the changes, ***or*** a comparative table showing the changes including all chemical names and CAS numbers (in addition to any Trade Names), suppliers names, addresses and contact details, appropriate Materials Safety Data Sheets (MSDSs) and the concentrations used
- full details of each change to a component, including the full formulation of each non-metallic material in contact with drinking water in the component, together with all relevant Material Safety Data Sheets etc.
- a revised Instructions for Use (IFU) document covering these changes and conforming to the current requirements for IFUs set out in Advice Sheet 2.
- for products made up of several components, e.g. water treatment units, tables clearly showing which component(s) is affected by the change
- Payment of £350

And as appropriate:

- full details of any change in the manufacturing process as a consequence of changed ingredients or any other reason
- full details of any changes in the quality management system
- the effects of the change(s) in terms of the surface area of material(s) in contact with the static volume of water within the product

DWI will assess the information and if satisfactory then product approval can be maintained, and DWI will confirm this acceptance either in writing or in electronic format. If the information is not satisfactory or further information, including any testing, is required, DWI will specify it in writing. The further testing may include testing to the requirements of BS 6920, leaching tests for specified chemicals or GCMS scan or both.

DWI will charge £350 for purely administrative changes, but may charge an additional £2,000 dependent on the complexity of the change.

5. Re-approvals

5.1 Change Requests made as Part of 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.

5.2 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.

6. Timescales

The time taken to agree to proposed changes will be dependent upon:

- the completeness and quality of the supporting information provided
- the need for any additional testing
- clearance of payment.