

# APPROVAL OF PRODUCTS FOR USE WITH DRINKING WATER

# **Advice Sheet 10**

# Natural and Traditional Products

#### DOCUMENT CONTROL

The only controlled version of this document can be accessed on the <u>DWI Website</u>. 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	Title
Sheet	
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 (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 <u>DWI website</u>.

#### **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 <u>DWI</u> 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 <u>The Water Supply (Water Quality) Regulations 2016</u> (Statutory Instruments 2016 No 614).
- b) Wales regulation 31 of <u>The Water Supply (Water Quality) Regulations 2010</u> (Welsh Statutory Instrument 2010 No 994 (W.99) and Amendment Regulations 2016 (No. 410 (W. 129))
- c) Scotland regulation 33 of <u>The Public Water Supplies (Scotland) Regulations 2014</u>
- d) Northern Ireland regulation 30 of <u>The Water Supply (Water Quality) (Amendment) Regulations (Northern Ireland) 2009</u> (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 <u>List of Products for use in Public Water supply in the United Kingdom</u>) is posted on the DWI website. Reference to "the List" throughout this publication refers to the most up-to-date version available from the

vebsite.

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 <u>Advice</u> <u>Sheet 1.</u> 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

Under the Water Supply (Water Quality) Regulations 1989, most traditional substances, including those based upon natural ingredients, used with water intended for human consumption (drinking water) came under the requirements of either regulation 25(1)(c) or 25 (1)(d) – see text below.

- 25.-(1) A water undertaker shall not, otherwise than for the purposes of testing or research, apply any substance or product to, or introduce any substance or product into, water which is to be supplied for drinking, washing, cooking or food production purposes unless -
  - (a) the Secretary of State has for the time being approved the application or introduction of that substance or product and it is applied or introduced in accordance with any conditions attaching to that approval; or (b) the undertaker is satisfied that the substance or product either alone or in combination with any other substance or product in the water is unlikely to affect adversely the quality of the water supplied; or
  - (c) the undertaker can demonstrate that the substance or product has during the period of twelve months preceding the making of these Regulations been applied or introduced (otherwise than for the purposes of testing or research) by a water authority or a statutory water company into water supplied by it for domestic or food production purposes; or
  - (d) the substance or product -
    - (i) was at any time before the commencement of these Regulations listed in the 15th Statement of the Committee on Chemicals and Materials of Construction for Use in Public Water Supply and Swimming Pools or in any supplement to that Statement issued before the making of these Regulations; and
    - (ii) is applied or introduced in accordance with any conditions referred to in that Statement or any supplement so issued or any such conditions as varied under paragraph (5) of this Regulation and any conditions imposed under that paragraph.

#### Sub-paragraphs (b) to (d) have effect subject to paragraph (4) below.

- (2) An application for such an approval as is mentioned in paragraph (1)(a) may be made by any person.
- (3) The Secretary of State may, if he decides to issue an approval for the purpose of paragraph (1)(a), include in the approval such conditions as he considers appropriate and, subject to paragraph (6), may at any time revoke or vary any approval he has previously given.
- (4) The Secretary of State may by notice given in writing to any water undertaker prohibit it for such period as is specified in the notice from applying to, or introducing into, water intended to be supplied for drinking, washing, cooking or food production purposes any substance or product which the undertaker would otherwise be authorised to apply or introduce by paragraph (1)(b),(c) or (d).
- (5) The Secretary of State may by notice in writing to water undertakers vary any condition contained in the 15th Statement or any supplement referred to in paragraph (1)(d)(I) or impose conditions as to the application or introduction of any substance or product listed in that Statement or any supplement.
- (6) The Secretary of State may -
  - $(a) \ revoke \ by \ an \ instrument \ in \ writing \ any \ approval \ given \ by \ him \ for \ the \ purposes \ of \ paragraph \ (1)(a);$
  - (b) modify any such approval by an instrument in writing by including conditions, or varying existing conditions;
  - (c) issue any such notice as is mentioned in paragraph (4);
- but, unless he is satisfied that it is necessary to do so in the interests of public health without notice, shall not do any of those things without giving all such persons as are, in his opinion, likely to be affected by the revocation or modification of the approval or by the issue of the notice at least six months' notice in writing of his intention.
- (7) Notice shall be given forthwith by the Secretary of State to all persons likely to be affected by the making of such an instrument as is mentioned in paragraph (6)(a) or (b).
- (8) At least once in each year beginning with the year 1990, the Secretary of State shall issue a list of all the substances and products in relation to which -
  - (a) an approval for the purposes of paragraph (1)(a) has been granted or refused;
  - (b) such an approval has been revoked or modified;
  - (c) a notice has been issued under paragraph (4),
- with particulars of the action taken.

#### 1.1 Traditional Products

These include substances and products that have been used in the past under the requirements of regulation 25 (1)(c or d)<sup>1</sup> in the collection, treatment and/or distribution of public water supplies, e.g. bitumen lined ductile iron pipes, or flexible rising mains for use in bore-holes. For further guidance and help see Section 3 of this Advice Sheet.

#### 1.2 Natural Substances and Ingredients

These include:

- a whole product (or the major component of a product), of natural origin, used in contact with water intended for human consumption, perhaps as part of water treatment, e.g. barley straw used for algal control in reservoirs, or tannin used in coagulants and flocculants
- an ingredient or component of another product, e.g. asphaltic bitumen used in semiporous coatings for the water contact surfaces of cement mortar lined ductile iron pipes (see FAO 9)

## 1.3 The Current Regulations

Under the current regulations the "grandfather rights" previously in place through regulation 25 (1)(c) and (d) were no longer available and such natural and traditional products are now subject to formal application for approval under Regulation 31 of the current Regulations – see Advice Sheet 1 for an overview of the requirements.

The following sections review of issues of concern and the approach now adopted to the approval of such products and ingredients.

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<sup>&</sup>lt;sup>1</sup> Or the Fifteenth Statement of the committee on chemicals and materials of construction for use in public water supply and swimming pools, dated March 1989, Department of the Environment.

## 2. Issues of Concern

#### 2.1 General

When considering these natural and traditional products and ingredients, the same basic assumptions have to be made that are used in the evaluation of new products for approval under regulation 31 of the current Water Supply (Water Quality) Regulations. These products are evaluated taking into account issues such as:

- the exposure of the product or ingredient to water intended for human consumption (both contact surface area to volume, and contact duration), and whether they fall under the requirements or regulation 31(4)(a) or 31(4)(b); for further advice refer to Advice Sheet 8.
- the degree of control that could be achieved over the quality and variability of a natural ingredient used in the product
- for products falling under the requirements of regulation 31(4)(a), the potential toxicity of compounds leaching into water from the product, based upon declaration of ingredients and or results of leachate studies, e.g. pesticides and/or herbicides, or compounds such as polycyclic aromatic hydrocarbons (PAHs)
- the potential (anticipated) overall risk to public health through drinking the water on contact with the product

## 2.2 Maintenance and Replacement Parts

There has been concern about continued use of some products by water undertakers on the basis of their past use, without problems; i.e. like-for-like replacement of traditional products that have been in use over many years. The Inspectorate has agreed that such a like-for-like replacement strategy is **not acceptable** unless the replacement has met the appropriate requirements of regulation 31 of the Water Supply (Water Quality) Regulations 2016, with the following exceptions:

- a) bespoke plant items previously approved under regulation 25 of the Water Supply (Water Quality) Regulation 1989 and held in storage for future use in order to maintain the plant
- b) service replacement low contact parts (small contact surface area or transient contact time, i.e. falling under the requirements of regulation 31(4)(b)) for obsolescent or obsolete products and plant previously approved under regulation 25, that are no longer available from the original manufacturer and/or supplier, and have not been assessed under regulation 31. For further guidance refer to Advice Sheet 8 and/or seek advice from the Inspectorate.

In both of these latter cases the use of these service or maintenance parts is permitted provided the water undertaker carries out a risk assessment to satisfy themselves of the continued fitness for purpose and safety of the component(s) for use in public water supplies. In all other cases full conformity with the appropriate requirements of regulation 31 of the current Regulations is required.

#### 2.3 Examples

Some examples of the approach that has been taken with both traditional products and natural ingredients are given in Section 4 of this Advice Sheet.

# 3. Applications for Approval: Requirements

In the main these are the same as those given in <u>Advice Sheet 1</u>, together with the appropriate requirements for the Instruction for Use document(s) given in <u>Advice Sheet 2</u>. Applications should be made on the appropriate form.

In the case of natural ingredients additional information is required as part of the application documentation, including details of:

- a) Source(s) of the natural ingredients or components
- b) The natural variability of the chemical makeup and nature of the ingredient (component)
- c) The analytical controls in place to ensure consistency of the ingredient (component)
- d) Analytical results from testing of the product during a minimum period of three months, demonstrating conformity with the requirements
- e) Potential interaction between the ingredient (component) or leachates from it, with chlorine in water, or in the case where contact is limited to un-treated water, the potential of leachates to react with chlorine later in the treatment process
- f) For ingredients or products based upon plants and extracts from them, what controls are in place over herbicides and pesticides use during their growth, harvest and subsequent storage of them.

# 4. Examples: Specific Products/Ingredients

The following examples highlight how these concerns have been applied to various product types, in evaluating whether:

- approval under regulation 31(4)(a) is relevant and/or possible
- the control of the consistency of the appropriate natural ingredient(s) could be achieved
- the degree of risk posed by the proposed use

<u>a. Asphaltic bitumen</u> – here the concern has been the potential degree of variability of the bitumen, and its potential leachates, arising out of the different open-market source of the bitumen used as the major ingredient (plus suitable solvents) to make bitumen based coatings and enamels. Interested manufacturers and suppliers of bitumen containing products to make a formal submission of their products for evaluation in a trace organic analysis of leachates by GC-MS general scan. Due to the low commercial margins associated with these products, no manufacturer has yet submitted any bitumen based product for formal evaluation under these requirements.

<u>b. Flexible rising mains for boreholes</u> – although these were used under the requirements of regulation 25 of the Water Supply (Water Quality) Regulations 1989, the Inspectorate has not yet been able to recommend any of these hoses for use under regulation 31 of the current Regulations, on the basis of the large numbers of (mainly unidentifiable) compounds leaching from the hoses into water. This has imposed particular operational requirements on water companies who have needed to replace hoses formally installed under the old Regulations, but have had to use an alternative solution.

<u>c. Vegetable oils (e.g. castor oil)</u> – used as an ingredient in some coatings. The Inspectorate has been advised to accept such ingredient without further specific test requirements for the ingredient, provided that they are of known quality, e.g. food or pharmaceutical grade and tested to demonstrate compliance with the appropriate requirements. Such acceptance does not cover, however, the normal testing requirements associated with the approval of any product under regulation 31(4)(a).

<u>d. Natural substances used in water treatment processes</u> – here the approach adopted has been to seek evidence of adequate quality control of the substance, including:

- substantive records of relevant analysis of manufactured batches of the product or ingredient over several months,
- details of chemical agents used to control pests and diseases during growth
- evidence of the efficacy of the product and the effects on water quality after treatment, including presence of leachates from the substance

To date satisfactory evidence has not been supplied for any such product to enable approval to be given.

<u>e. Barley straw used for algal control</u> – this has been accepted, provided that it had been grown without the use of pesticides, herbicides and related products – see Section 7.1 of <u>Advice Sheet 3</u>.