



APPROVAL OF PRODUCTS FOR
USE WITH DRINKING WATER
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CHARGING FOR

APPROVAL OF PRODUCTS FOR USE IN CONTACT WITH

WATER INTENDED FOR HUMAN CONSUMPTION

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1 INTRODUCTION

This guide has been prepared as a general introduction for manufacturers and suppliers of products used in contact with water intended for human consumption and others who have an interest in how the charging scheme will operate. It explains the approval process and how charges will be made and gives an indication of the individual charges an applicant may have to pay.

It has been prepared on the basis of The Water Supply (Water Quality) Regulations 2000, which came into force on 1 January 2004, as amended and in particular The Water Supply (Water Quality) Regulations 2000 (Amendment) Regulations 2007 (SI 2007/2734), which came into force on 22 December 2007. The guide can be accessed on the Internet at the following website address:

http://www.dwi.gov.uk/stakeholders/legislation/ws_wqregs2000amend2007.pdf

If you manufacture or supply a product for use in contact with public drinking water supplies (including water before and during treatment) in the UK, then this guide is for you. Whether you are a small, medium or large manufacturer or supplier you need to be aware of the duty on water undertakers and combined licensees to comply with certain requirements set out in Regulation 31, in respect of any product applied to or introduced into the water.

In addition to the English Regulations given above similar regulatory requirements apply in Wales, Scotland and Northern Ireland:

Regulation 31 of the Water Supply (Water Quality) Regulations 2001 in Wales
Regulations 27 of the Water Supply (Water Quality)(Scotland) Regulations 2001
Regulations 30 of the Water Supply (Water Quality) Regulations (Northern Ireland) 2007

One means of complying with these requirements, which is appropriate for some products, is through the approval process. The Drinking Water Inspectorate (DWI) operates the approvals process on behalf of the Authorities in England and Wales and provides technical and administrative support to the Authorities in Scotland and Northern Ireland. In practice this means that all approvals considered in the UK follow the same process, are administered by DWI but separate letters of approval are issued by the Authorities in Scotland and Northern Ireland.

Charges are calculated in accordance with Defra policy on charging and aim to recover the full cost of providing the service but no more. Details of these costs are given in Annex 1.

A general Guide to the approvals process, and the more detailed technical guidance which should be used when making an application is provided on the DWI website www.dwi.gov.uk

2 WHAT PRODUCTS REQUIRE APPROVAL

2.1 General

In general all products applied to or introduced into drinking water, including water before and during treatment, could require approval. However, there are a number of important exclusions. These exclusions are:

- Water treatment chemicals which comply with an appropriate BS EN
- Products solely for use within buildings
- Products with only a small surface area in contact with water or if contact is only transient
- Products which are not intended to come into contact with drinking water
- Treatment chemicals (and in some situations other products) for use solely in an emergency

Mixtures of two or more water treatment chemicals (whether or not any or all of them conform to a BS EN) require approval.

Products used solely within buildings are regulated under a different regime. Approval of these products is administered by the Water Regulations Advisory Scheme (WRAS). More details can be found on their website www.wras.co.uk

2.2 Other approvals

In addition to the above, approval is also needed:

- Before a product may be applied to or introduced for the purpose of testing or research
- For specialist one-off uses.
- Applications for these types of approval are normally made by the water undertaker or combined licensee rather than the manufacturer or supplier and in the case of testing or research must be made by the undertaker or licensee.

Application is also required to be made for modification of an existing approval because of:

- Change of name of the approval holder
- Change of name of the product
- Change of formulation of the product or an ingredient of the product
- Change to the content of the Instructions for Use
- Change of or addition of an extra use of the product

Approval holders are required to advise DWI of other changes eg change of address, change of contact details but these do not require an application to be made. Some other changes (eg change of manufacturing site) may require an application to be made.

3 THE APPROVAL PROCESS

To qualify for approval a product must be intended for use in contact with public water supplies in the United Kingdom at any point from the source to the boundary of the premises to which water is supplied. From Jan 2010 products in contact with private water supplies will be similarly included.

Products in contact with water beyond the boundary should be approved for that use by WRAS (see 2.1 above).

Products with low contact ratio with the water (that is products with only a small surface area in contact with the water and/or only transient contact) do not require approval. These are covered by, less onerous, requirements in line with the reduced risk of them adversely affecting water quality.

When the Inspectorate receives an application form and payment of the appropriate fee, it checks the form for completeness, requests any outstanding information and when complete assesses the information. On occasions further information may be required and will be requested directly. Sometimes at this early stage expert advice may need to be sought, such as expert toxicological advice. Once any advice has been obtained the Inspectorate will inform the applicant of the outcome with either the reason for not considering the product suitable for approval or information requirements that can be identified at this stage.

4 CHARGING ARRANGEMENTS

4.1 What work will be chargeable?

Details of activities attracting charges are set out at Annex A but, broadly speaking, the main chargeable activities are:

- The preliminary assessment of all new applications to ensure that they qualify for consideration for approval
- Evaluation of information provided for all applications, including results of initial testing, to ensure that it is complete and assess any potential health risks and further tests that may be required
- Evaluation and processing of major changes to approved products, such as change of in formulation, change in method of manufacture
- Liaison with the applicant and testing laboratory over further testing requirements
- Evaluation of the test report and toxicological advice to determine suitability of product for approval
- Completion of approval process, listing of approved products, maintenance of website

NOTE: DWI does not provide a consultancy service for applicants

4.2 What work will NOT be chargeable?

Excluded from any charge made under these provisions are:

- Changes to existing approvals initiated by DWI
- General advice on the approval process
- Changes to approval holders contact details

Some changes to currently approved products, such as change of supplier for a single ingredient may or may not attract a charge. This is because some of these changes involve only a simple change to records, while others may involve extensive work, possibly including further testing. In such cases the approval holder should contact DWI with details of the change. DWI will then advise whether the information provided is sufficient, in which case no charge will be incurred, or whether a formal application is required, in which a charge will apply.

5 FEES

5.1 Powers to make charges

Section 69 of the Water Industry Act 1991 gives the Secretary of State powers to make regulations for the preserving of drinking water quality. Subsection (3) specifically includes in those powers the making of regulations in respect of processes, substances and products that may affect the quality of any water and subsection 4(g) gives powers to require prescribed charges to be paid to persons carrying out functions regulated under subsection (3).

Regulation 31 was amended in 2007 to include a new subclause

“(13) The Secretary of State may—

(a) by notice served on the person who makes an application for approval under paragraph (4)(a), require the person to pay him a charge which reflects the administrative expenses incurred or likely to be incurred by the Secretary of State in connection with the application; and

(b) in determining the amount of any such charge, adopt such methods and principles for its calculation as appear to him to be appropriate.”.

5.2 Basis and amount of fees for applications

The exact data requirements for all the different types of application and the procedures for handling them are finalised. Based on a estimate of the time required for each of the steps in the process and the historic distribution of the effort involved in dealing with individual applications, estimates of costs have been produced and have been used initially for setting the level of fees. Data has been gathered to allow an accurate assessment of actual costs to be made. Data is available to make an accurate assessment covering the full range of types and complexity of application and the fees are set based on this data.

The way in which DWI has approached the identification of the relevant costs for inclusion in the fees follows the guidance in HM Treasury's Fees and Charges Guide.

The fees payable are:

Preliminary assessment of a new application	£350
Main assessment	£2000
Further Analysis assessment	£800

5.3 Who will be subject to the fees

The applicant is responsible for all fees due. No approval letters will be issued by DWI until the relevant fee has been paid.

5.4 Methodology used for calculating the fees

The cost of each type of application has been calculated, having reference to the amount of staff time at each grade that will be required to evaluate an application. DWI has operated a work recording system which has generated the relevant information to allow an accurate review of charges. The charges are calculated in accordance with HM Treasury's Fees and Charges Guide and include the full cost of all the resources used in carrying out that chargeable activity.

The costs included are as follows:

- i) *Gross Salaries of Staff*,
 - gross salaries of direct staff;
- ii) *Gross Salaries of Operational Management and Strategy*,
 - gross salaries of indirect staff;
- iii) *General Administrative Expenditure*,
 - Accommodation costs;
 - Travel and subsistence;
 - Staff development and training;
 - Office services (for example, IT, postage and Telecommunications);
 - Services bought from external suppliers (for example specialist technical advice)
- iv) *Corporate Services*,
 - Common services (for example, finance, personnel);
- v) *Capital Charges*,
 - Depreciation of fixed assets, costs of capital and insurance.

6 ADMINISTRATIVE AND FINANCIAL ARRANGEMENTS

For all new applications, the applicant should initially submit an application form together with the Tier 1 fee of £350. If payment is by cheque, it should be enclosed with the application. For all other payment methods, an invoice will be generated by DEFRA finance department. DWI will then assign the application a reference number and issue it to the applicant. This reference number will be unique and remain with the product throughout the application and throughout the life of an approved product. All payments and other correspondence must bear this reference number, otherwise unnecessary delay may result. For low risk products such as stainless steel and recognised grades of Polyethylene, the Tier 1 charge is the only charge payable in order to process the application.

For all new applications that are accepted as suitable for approval but regarded as high risk, the applicant will be issued with an invoice for any further charge at the Tier 2 fee. Once all information has been received (including any confidential information received directly from suppliers of ingredients and components) DWI will continue to process the application.

If DWI advises the applicant or approval holder that further testing of the product is required (leaching tests), a further assessment fee will be incurred. In such cases DWI will issue the applicant with a further Invoice for the relevant fee (the Tier 3 fee). This fee should be paid by the applicant when the further test report is submitted to DWI for assessment. No extra charge will be incurred if yet further testing or further information is required to be assessed before a decision can be made.

Payments can be made by cheque made payable to "DEFRA", Purchase Orders, Debit card, credit card, BACS and CHAPS payment are available and listed on the application form. Payments are due within 28 days of the invoice date.

7 QUERIES AND COMPLAINTS PROCEDURE

7.1 Queries

All queries, including disputes about fees, should first be addressed to the DWI's Regulation 31 Team who will attempt to resolve the issue with the enquirer or complainant.

7.2 Complaints

All complaints about the approval process, including disputes about fees not resolved satisfactorily by the Regulation 31 Team, should be addressed to the Regulation 31 Section Head who will attempt to resolve the issue with the complainant.

Complaints about the actions of members of the Inspectorate, and unresolved complaints about the approval process, should be made to the Chief Inspector. In the first instance all complaints will be investigated by the Chief Inspector or a Deputy Chief Inspector. A response to the complaint will be made within twenty working days of the date it is received in the Inspectorate. The response will include details of what action has been taken. If it is not possible to make a response within 20 working days because of the need for further information or investigation an interim response will be made.

If the complainant is not satisfied, the matter will be reviewed by the Director of the Water Directorate in the Department Environment, Food and Rural Affairs who will, if the matter is scientific or technical, appoint an independent specialist to advise them, if necessary.

7.3 Contacts for advice and guidance

Should you need advice on the operation of the charging system or have a specific query, please Email or write to DWI at:

Reg31enquiries@defra.gsi.gov.uk

Area4a, Ergon House, Horseferry Road, London, SW1P 2AL

Tel: 0300 068 6403/5029