guardians of drinking water quality

APPROVAL OF PRODUCTS FOR USE WITH DRINKING WATER

Advice Sheet 1

Overview of the Application Process

DOCUMENT CONTROL

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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:

E-mail:reg31.enquiries@defra.gov.uk
Telephone: +44 (0)300 068 6400

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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.

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

This Advice Sheet deals with the approval system for substances and products and generally refers to these as chemicals and construction products used in contact with public water supplies in the UK.

The relevant regulations for public drinking water suppliers concern the introduction of substances and products (including construction products) and processes for use in the treatment and provision of public water supplies. They implement the requirements of Article 10 of the European Union Directive 98/83/EC on the quality of water intended for human consumption, in respect of **substances and materials used in the preparation and distribution of water up to the point of delivery to premises**. They do not implement the requirements of the Directive with respect to products used solely **within premises (water supply systems within buildings)** – these products are covered by separate regulatory requirements.

The relevant regulations require that public drinking water suppliers shall not apply or introduce any substance or product into public water supplies unless one of the requirements of this regulation is met. One of these requirements is the substance or product has been **approved** by the Authorities.

The DWI operates the approval system on behalf of the English and Welsh Authorities. DWI can accept applications for approval of products used both before and at the treatment works and in water distribution systems up to the point of delivery to premises. DWI cannot accept applications for products used solely in water systems within premises and cannot deal with enquiries on such products – such applications and enquiries should be made to the Water Regulations Advisory Scheme.

2. Scope of the Approval System

2.1 Treatment Chemicals and Associated Products

a) Applications are considered for those chemicals and associated products, such as filtration and adsorption media used in contact with water at water treatment works and within the water supplier's distribution system, that are not covered by a published BS EN standard.
b) Applications for mixtures of chemicals (whether or not conforming to a relevant BS EN standard) are also considered.
c) Individual chemicals and media that conform to an appropriate BS EN standard may be used without the approval of the Authorities provided all specified national conditions of use are met. These conditions are set out in Annex 2 of the "List"
d) Disinfectants and related chemicals used in emergencies – see Section 3 and Annex A of Advice Sheet 9 for further guidance.
e) Disinfectants for continuous use – must be approved as a biocide by HSE before an application for approval with drinking water - see Section 2.2 of Advice Sheet 3

2.2 Construction Products

Applications are considered for all non-metallic construction products used in contact with water, in water treatment processes, water supply pipelines (including raw water pipelines) and drinking and raw water storage installations (see also Advice Sheet 7).

Advice concerning applications for approval of metallic materials and products is given in Section 5 of Advice Sheet 5 and in Advice Sheet 8 .

It is the responsibility of users of any construction products that will be in contact with water intended for human consumption to have satisfied themselves about the compatibility and/or fitness for purpose of the product for the particular proposed use, taking into account water quality, flow rates, temperatures etc.

3. Applications for Approval

The progress of submissions from applicants is most often delayed by inadequate or incomplete information. Before making any submissions applicants are encouraged to contact Regulation 31 Enquiries. It should be noted that DWI cannot provide consultancy assistance in the completion and submission of an application for approval; however for novel products or complex product applications, a meeting with DWI may be required. Applicants may find it helpful to engage/commission appropriately experienced independent consultants, such as from one of the designated test laboratories, to assist with their application.

3.1 General Requirements

Normally the following minimum information is required for all applications – **this must be provided in English and it is the applicant's responsibility to translate, or have translated, any information in another language:**

a. A completed application form relevant to the product – see "a" below
b. Full disclosure of formulation details for the product and *all* individual ingredients of the product, including *all* water contact components, and *all* associated Material Safety Data Sheets (MSDSs)
c. Details of the quality management system for the manufacture and supplier of the product
d. An Instructions for Use (IFU) document – see "b" below
e. Results of BS 6920 testing for all non-metallic water contact materials (see Annex B) or evidence of a current listing by the Water Regulations Advisory Scheme in their web-based Water Fittings and Materials Directory – see "c" below.
f. Payment for the application by cheque, credit or debit card, BACS or CHAP's. For details of costs see table in section 3.6

Additional information, such as extended leaching tests and toxicological data, may be required for those products that are considered to represent a potentially higher risk to drinking water quality and the health of consumers because of their type, composition or method of application, such as linings applied and cured *in-situ.*

a. **An Application for Approval** may be made by any person and must be submitted on the appropriate application form which can be obtained from the website. A separate application must be submitted for each product or group of related products. Completed application forms, together with supporting information, should be emailed to DWI.

b. **The Instructions for Use (IFU)** for the product is an essential document for the approval process and must meet all the appropriate requirements set out in Advice Sheet 2. Any approval given for the product will be subject to the application and use of the product as specified in this IFU.

c. **BS 6920 testing**. Normally DWI needs to receive a current (issued within the last 5 years) BS 6920 test report (or equivalent European test report) for all non-metallic materials used in construction products (and other products such as membrane filters and some filtration/adsorption media) before it can specify its own test requirements that may additionally be required. (BS 6920: 2000 Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of water).
Notes:

i. for pipes (and their fittings, if appropriate) the odour and flavour assessment (BS 6920-2.2.2) test must have been undertaken by filling test lengths of pipe, incorporating appropriate joints (e.g. heat welds, solvent welds) of the smallest diameter for which approval is sought – this additional testing (on jointed pipes) is not normally carried out for approval of pipes under the Water Regulations Advisory Scheme (WRAS)/BS 6920 requirements.
ii. BS 6920 reports more than five years old, or within six months of the five year audit date (see note "iii" below) cannot be used in support of an application for approval for use within the water supplier's distribution system.
iii. WRAS listing numbers (for products and materials that are used in water systems within premises that have been subject to BS 6920 testing) that are more than 5 years old, or are within six months of the five year audit date, cannot be used in support of an application for approval for use within the water supplier's distribution system.

Details of laboratories accredited for BS6920 testing can be found on the website.

DWI will also consider test reports (in English) from other European Economic Area (EEA) states in support of applications (see Annex C). However, if such test reports do not include assessments of:

a) potential for adverse effect on odour and flavour of both chlorinated and chlorine-free water[1] ***and***
b) potential to support microbiological growth

It will be necessary for the BS6920 odour and flavour, and growth of aquatic microorganism's tests to be carried out, as a minimum.

[1] If the product is a plastic pipe, test samples for the odour and flavour assessment must include appropriate joints, e.g. heat or solvent welded joints or mechanical couplings.

3.2 Supplier Co-operation

Applicants should tell their suppliers of ingredients or components of their intention to apply for approval and gain their advance co-operation with the provision of confidential formulation information, which should be sent directly to the DWI. All documents must be in English, or be accompanied by a certified translation.

Note: always ensure that your suppliers clearly identify any information they provide with your company and product name, and citing the DWI application number.

3.3 Confidentiality

Section 206 (Restriction on disclosure of information) of the Water Industry Act 1991 (WIA)[2] makes it a criminal offence for anyone to disclose information, with respect to any particular business which has been obtained by virtue of any provisions of the WIA and which relates to the affairs of an individual or particular business [3]. In line with the WIA and government policy, the DWI has procedures in place to ensure that information regarding product formulation and ingredients remains confidential.

As the DWI and its expert advisers are already bound, by law, to keep information confidential and cannot contract out of these obligations, the DWI and its expert advisers cannot enter into confidentiality agreements. However, any company confidential information will be treated as covered by the restriction on disclosure under section 206 of the WIA.

DWI may need to copy parts of this material to its advisers and its appointed analysts, and possibly other colleagues, for the purposes of the application; it may not be able to process the application without doing so.

DWI may also require a third party to provide "confidential" information. If the third party refuses to provide this information, it will not be possible to progress the application; the third party can send confidential information directly to the DWI.

The designated test laboratories may be willing to enter into confidentiality agreements with applicants and their suppliers, if required.

Applicants should take appropriate precautions to ensure that confidentiality is maintained during the transmission of company confidential information to DWI, or their designated test laboratories.

For further information see FAQ3.

[2] A non-consolidated version of the WIA can be viewed here.
[3] Exceptions include: consent of the individual or business concerned and disclosure which is for the purpose of facilitating the performance of certain statutory functions of various bodies (including the Secretary of State, Ofwat and local authorities) – section 206(1) and section 206(3)(a) of the WIA respectively.

3.4 Timescale

The sequence of steps in the approval process is set out in Figure 1. The time taken to obtain approval is dependent on many factors, including:

a) whether the product is a treatment chemical or a construction product
b) whether the product is potentially considered to be a low or high risk to drinking water quality or consumers' health
c) the completeness of the documentation submitted to DWI
d) the time taken to obtain confidential formulation information from the applicant's suppliers
e) the complexity of the product and its method of use
f) the results of leaching tests (including BS 6920 testing) and the quality of the leaching test report

In view of the various factors it is not possible to give specific assurance about the time taken to determine an application for approval. DWI cannot assume responsibility for the time taken by the applicant (and any of the applicant's suppliers) to submit a completed application of sufficient quality.

It is essential that applicants plan ahead and ensure that their applications (including all supporting documentation) are complete and meet all the appropriate requirements. There is no point in providing an incomplete or inadequate application (including supporting documentation) – it will be returned with a brief list of what is missing or inadequate.

IMPORTANT NOTE

DWI cannot be held responsible for any financial loss arising as a result of the time taken to handle an application, including the potential need for additional information or additional testing work required during the processing of the application.

3.5 Cost of Application

Type of application	Minimum cost
Applications pipes made from recognised materials	£350
Applications for stainless steel products, including pipes	£350
Applications for pipes with recognised factory applied coatings	£350
Applications for treatment chemicals where the mixture of ingredients all conform to BSENs	£350
All other applications	£2350

For complex applications that require further leachate testing a third charge of £800 will be required in order to complete the approval process. We can receive payments via the following routes but invoices will be issued on receipt of an application:

- Cheques made payable to: DEFRA
- Debit or Credit card
- CHAPS or BACS payment

All payment details are available on the application forms available on the DWI website. An estimate of the costs for any testing required can be obtained from the chosen designated test laboratory(ies) once the test requirements have been notified by DWI.

3.6 Formulation requirements

The product

The following product formulation information is required, **in English:** –

a. details of all constituent chemicals/ingredients of the product
b. chemical (not trade) name of each ingredient
c. CAS number(s) of each ingredient
d. Concentration of each ingredient present in the product - the sum of the concentrations must come to 100%
e. the Material Safety Data Sheets for each ingredient
f. the method(s) of manufacture and details of the intended use.

The ingredients

The following formulation details of each of the individual ingredients of the product are required (where they contain more than one chemical), **in English**–

a. details of all constituent chemicals/ingredients
b. chemical (not trade) names
c. CAS number(s)
d. concentrations present in the ingredient - the sum of the concentrations must come to 100%
e. the name of the supplier of the ingredient – where more than one source is used all alternative suppliers should be named
f. the relevant Material Safety Data Sheets (including from each supplier, in the case of alternative sources)

When the product consists of a number of components, as construction products often do (such as a membrane filtration unit), the information specified above is required for each component.

Applicants may not be able to supply all the necessary formulation details of the ingredients of their products, due to commercial confidentiality. This often applies to construction products made of several components. In these circumstances, it will be necessary for the applicant to ask their supplier (or suppliers) to submit the information directly to DWI in confidence. **It is the applicant's responsibility to request information from their suppliers and to ensure that the appropriate information is provided.** Applicants should inform their suppliers of the intended use of the information. Suppliers will need to know that if leaching tests are specified, it may be necessary to disclose the chemical identity of some specific components of the formulation to the test laboratory.

Whilst the chemical names of individual chemicals present in ingredients may be provided to the test laboratory, other information will not be disclosed to the test laboratory without the supplier's authority in writing.

IMPORTANT NOTES

a. It is recognised that the Material Safety Data Sheets (MSDS) do not necessarily provide a full declaration of all components and their suppliers; therefore submissions must include a full (confidential) declaration from each supplier of each of the ingredients (including minor ingredients/components) of the product (and the name of the respective suppliers), and where necessary, of each of the sub-ingredients.

b. Applications that contain incomplete information will not be considered for approval.

3.7 Alternative Ingredients

For good commercial reasons it is often desirable to have several sources for one or more of the ingredients of materials. However, approval under the requirements of regulation 31 is granted on the basis there will be no changes in the nature or source of the ingredients used in products. If only one source is included in the initial application, any final approval will be based upon the sole use of this source, and adding an additional source will necessitate a request for a change to the approval from DWI.

Therefore you are strongly advised to consider any likelihood of wanting to use alternative suppliers for one or more of the ingredients in products and to include these with your initial approval application. In this latter case we will require full formulation details from each of the proposed suppliers of the ingredient(s). Some (usually minor) additional testing may be required to cover the alternative supplier(s).

3.8 Reworked/Recycled Products/Ingredients

DWI accepts that in many cases good manufacturing practice and economic considerations lead to the practice of using reworked/recycled materials in the manufacture of thermoplastic products ranging from pipes and their fittings and ancillaries, to thermoplastic elastomer (TPE) seals.

Note: the only reworked/recycled material acceptable for use in products in contact with water intended for human consumption under regulation 31(4)(a) shall meet ALL of the following requirements –

- Be derived solely from the production line for the final product for which approval is sought, *and*
- Be subject to no change whatsoever (e.g. addition on any ingredients) and only subject to minimal processing, e.g. re-grinding, *and*
- Be under the full control of the manufacturer at all times, e.g. shall have been within the specific product manufacturing facilities at all times.

The use of any other reworked/recycled material, including that from other production lines or sources, is not acceptable for consideration under regulation 31 (4)(a). Where a product comes under the requirements of regulation 31(4)(b), the approach to the use of recycled ingredients set out in Advice Sheet 8 applies.

3.9 Prohibited Substances

Lead

The Government policy towards the use of lead in construction products is that it should be avoided whenever alternative safer products are available. Section G 2.1 of the Guidance issued by the Department of the Environment, Food and Rural Affairs (DEFRA) for the Water Supply (Water Fittings) Regulations 1999 clearly prohibits the use of lead in products used in building water systems. Since December 2003, in relation to the Water Supply (Water Quality) Regulations, the use of PVC-U containing lead based compounds in the manufacture of water supply pipes has not been acceptable in the UK, and only "lead-free" PVC-U pipes are acceptable for use with water intended for human consumption.

DWI is aware that some lead-containing PVC-U pipes and fittings, such as those used in treatment plants, including membrane treatment elements and related systems, continue to be used in some other Member States, and are proposed for use with water intended for human consumption in the UK. After due consideration, DWI has agreed that such products could not be approved under regulation 31(4)(a) or for use in water treatment plant (regulation 31(4)(b)), unless the PVC-U used to make them is "lead-free".

Coal-tar derived bituminous substances

These too are prohibited under Section G 2.1 of the Guidance issued by the Department of the Environment, Food and Rural Affairs (DEFRA) for the Water Supply (Water Fittings) Regulations 1999 and cannot be accepted for use in contact with water intended for human consumption.

Dyes

Where a dye is used to colour a treatment chemical, but is not an active ingredient, a food grade dye should be used wherever possible.

4. Leaching Tests

a) *Leaching tests and analysis* of leachates are required for many applications, e.g. most construction products, membrane filter units etc.
b) *Test Analysis*. The specification for leachate analysis is based on the formulation of the product and its method of use.
c) *The analysis*, which involves the identification and quantification of specific potentially toxic substances and a general screen by GCMS (identification and semi-quantification) for other substances, provides the basis for the DWI and its expert advisers to evaluate whether use of the product in contact with water might affect drinking water quality, particularly in regard to its aesthetic quality or potential risk to the health of consumers.
d) *Test Water*. Normally preparation of leachates will be undertaken using test water that has no addition of free-chorine, together with test water containing 1mg/litre free-chlorine and final approval would be for use with all types of water intended for human consumption.
e) Where a product will only be used in water collection or treatment up-stream of the first point of chlorination, testing can be undertaken using test water with no addition of free-chlorine. In this case leachate preparation will be undertaken in duplicate, and the Inspectorate may require chlorination of one of the sets of leachates before analysis; any approval subsequently granted would normally be limited to use with unchlorinated water only.

Advice should always be obtained from DWI before any leachate studies are undertaken.

4.1 Test Samples

Applicants are advised to liaise with their chosen designated test laboratory concerning the choice and/or preparation of test samples taking into account –

a) The general requirements of BS EN 12873 Part 1, 2, 3 or 4
b) Any specific requirements specified by the DWI
c) For factory made products the elapsed time between test sample manufacture and start of testing – this should be representative of the shortest time likely to be encountered between manufacture and installation and use.

4.2 Start of Testing

a) Applicants are normally advised not to commission leaching tests before being notified by DWI about the type of leaching test and the analysis to be performed. Furthermore applicants must ensure that tests are carried out in accordance with those instructions.
b) Leachate studies on test samples of site applied and *in-situ* applied products should start immediately after completion of the minimum cure period specified in the Instructions for Use, including any relevant pre-commission treatments. See also Section 7 of BS EN 12873-2.
c) Leaching tests must be carried out by a designated test laboratory.

d) Applicants should note that use of a designated test laboratory does not guarantee that a test report will be accepted without question. From time to time it is necessary to ask for clarification of data contained in test reports. In certain cases, it may be necessary

to ask for additional tests to be carried out, particularly where the test report indicates significant concentrations of unidentified substances.

e) Failure to be able to identify, or account for the source of unidentified substances in the general screen by GCMS can present a significant obstacle to obtaining approval.

4.3 Test Reports and Evaluation

These must be clear, unambiguous and supported by appropriate quality assurance data. Failure to satisfy these requirements will delay processing of an application and may lead to refusal of approval by DWI. Guidance on reporting requirements is given on the DWI website.

Upon receipt, the final laboratory test report is submitted to the analytical expert for evaluation and confirmation that all the procedures have been correctly carried out. If the report is deemed unsatisfactory, the test laboratory will be asked for comment and/or correction, or, in the worst case, re-analysis. In some cases the test results may lead to the requirement to carry out additional testing before the outcome of the application can be determined. If either of these are needed, they will inevitably lead to a delay in the approval process.

If the analytical expert is satisfied with the report, it is then passed to the toxicologist for assessment of the leachate results and any possible health risk to drinking water. This assessment takes into account where the product is used. The toxicologist may require information on specific analytes; this could include toxicological data and long term exposure data, together with additional specific testing related to the leachate test results of the GC MS general survey.

Once the final assessment has been received, the final assessment of the product application can be made.

5. Requirements for Toxicity Data

The DWI may ask for toxicity data to help assess the significance on consumers' health of substances present in the product or identified in leachates. These substances may be components of the product, impurities or by-products of the manufacturing process or substances formed by the reaction of the product or its ingredients with substances present in water. Such data may be available in published literature but is more frequently held by manufacturers in the form of unpublished studies. It is the applicant's responsibility to approach manufacturers for this data; DWI can act as an intermediary if the manufacturer is unwilling to disclose the data to the applicant. Toxicological assessment principles are set out in Figure 2.

In cases where analysis for a specific substance is not technically feasible, the DWI may be prepared to consider a worst case assessment of the likely concentration of the substance in the leachate. If such calculations become necessary DWI will advise on the methodology to be followed by the applicant.

A tap calculations are required in the GCMS test report and these will be taken into account as part of the process.

6. Approval

Before a product can be approved by the Authorities, DWI and its expert advisers must be satisfied that use of the substance or product will not cause any adverse effect on drinking water quality or present a risk to consumers' health. DWI does not consider whether a product is fit for its intended purpose and approval by the Authorities must not be misconstrued as a favourable assessment of the performance or merits of any product.

Approval letters, which contain conditions of approval, make it clear that approval only relates to methods of application or use, set out in the Instructions for Use (IFU) documentation submitted to DWI. A condition of approval requires that the product is installed and used solely in accordance with the IFU document, which must be made available to water suppliers or combined licensees by the approval holder. Instructions for Use must be contained in a uniquely identified controlled document and any revisions must be notified to the DWI (see Advice Sheet 2 for further information and help).

Approvals will have a 5 year lifespan. Three months prior to this the approval holder will be sent a reminder to provide details required to have the approval continued.

Details of approvals, including any conditions of approval, are published in the "List".

6.1 Approval Claims

Approval of products is given by the Authorities; DWI operates the approval system on behalf of the Authorities. DWI does NOT approve products, and claims to this effect are not acceptable. Information about acceptable claims for approved products in England and Wales is given on the FAQ2

6.2 Refusal, Modification, Revocation or Review of Approval

It may be necessary to advise the Authorities that approval should be refused, revoked or modified. When approval of a substance or product is refused, or if a proposed change to an approved product cannot be agreed, a refusal letter is issued, the fact of refusal is published on the DWI website in the "List". Similar arrangements exist for the notification of revocation or modification of approvals.

The DWI carries out a rolling review of all approvals. A product specific review may be undertaken in the light of new information concerning possible health effects. At least six months' notice of any subsequent modification to, or revocation of approval is normally given. However, approval may be revoked without notice in the interests of public health, and water suppliers notified of the revocation with immediate effect.

7. Changes to Approved Products

For further information on changes and the appropriate charges see Advice Sheet 4.

8. Application Procedure

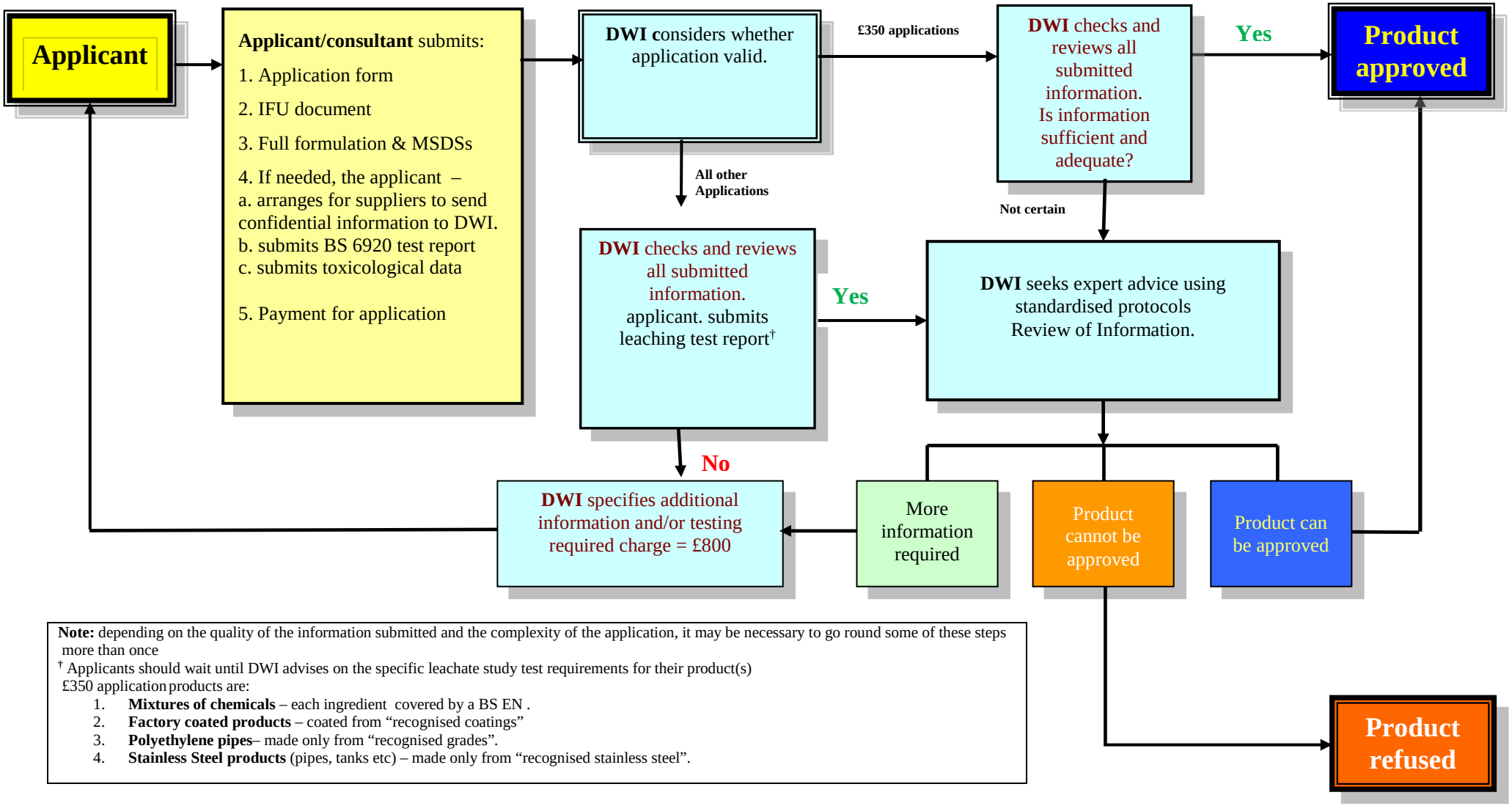
Applications to the DWI should be made using the appropriate product specific application form. A series of forms are available from the website. There are specific instructions and guidance given on the application forms to help to ensure that applicants provide the DWI with all the information required about the particular product type; this guidance should be followed in with reference to the relevant Advice Sheets.

The completed form and supporting product information specified (Instructions for Use, Material Safety Data Sheets etc) should then be submitted electronically to the DWI's Regulation 31 Enquiries.

In the case of Material Safety Data Sheets and relevant supporting reports hard copies may be sent to the address listed in the Preface.

The overall approval process is illustrated, diagrammatically in Figure 1.

Figure 1. **Outline of approval process**



Note: depending on the quality of the information submitted and the complexity of the application, it may be necessary to go round some of these steps more than once

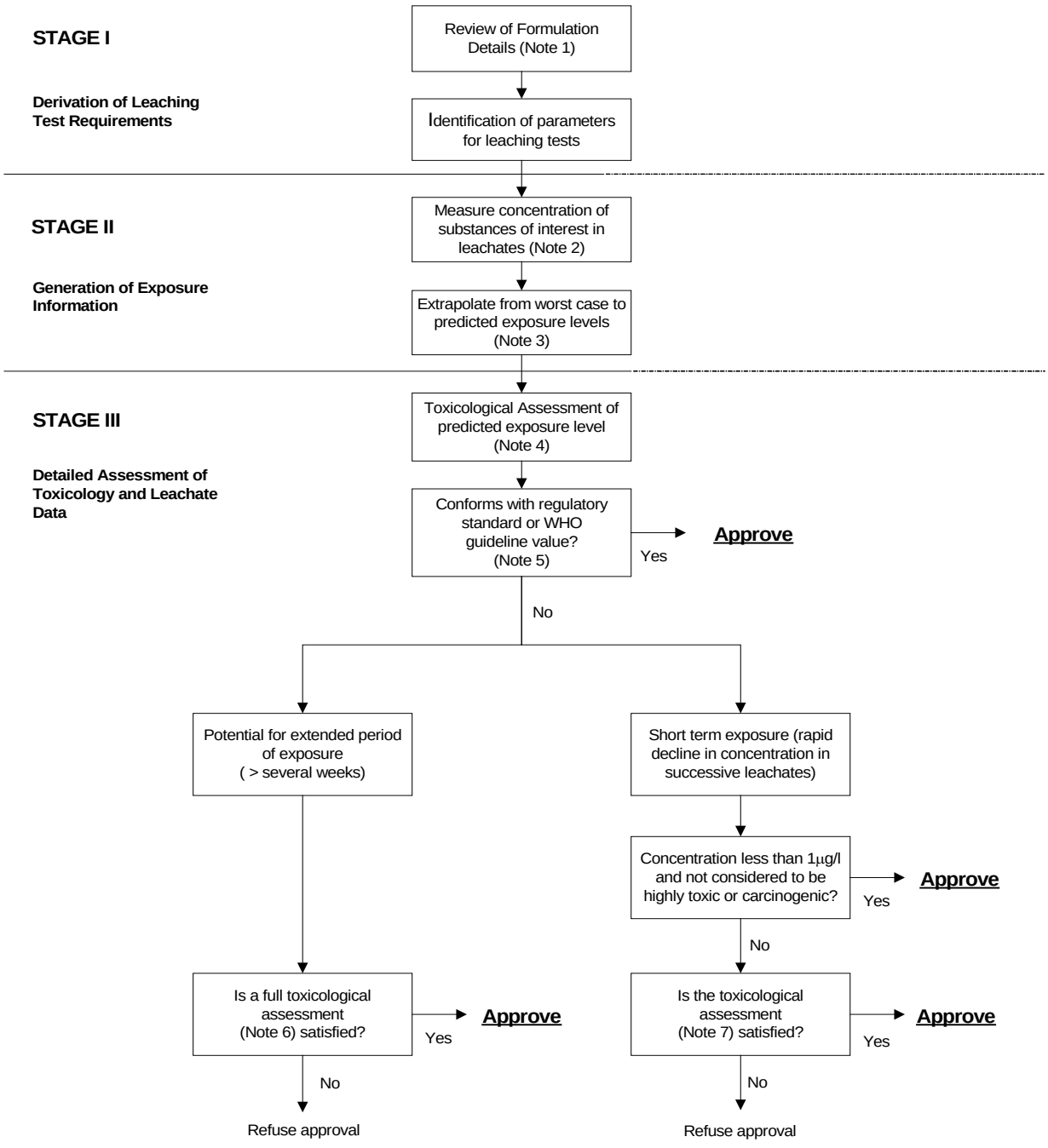
† Applicants should wait until DWI advises on the specific leachate study test requirements for their product(s)

£350 application products are:

1. **Mixtures of chemicals** – each ingredient covered by a BS EN .
2. **Factory coated products** – coated from "recognised coatings"
3. **Polyethylene pipes**– made only from "recognised grades".
4. **Stainless Steel products** (pipes, tanks etc) – made only from "recognised stainless steel".

Figure 2

TOXICOLOGICAL ASSESSMENT OF LEACHING TEST DATA



See the next page for associated notes for this Figure.

Notes for Figure 2.

1. Any substance that is found to be present in leachates at a concentration providing a human exposure lower than a tolerable exposure value will generally not require further evaluation of health risks.

2. Leaching tests are carried out under worst case conditions of product surface area to volume of test water. A series of leaching tests is carried out over 1-9 days in order to characterise the decline in rate of leaching. A separate health assessment is performed for each substance of interest. In some cases additional leaching periods may be requested by the toxicity adviser – see Annex D.

3. Information on the predicted consumer exposure levels may be provided by applicants to assist the DWI and its expert advisers with its assessment. These predictions should normally be based on conservative dilution factors, which take account of the exposure conditions during actual use of the product.

4. Where the applicant has not provided any estimate on predicted exposure levels, or the basis for a predicted exposure is considered to be inadequate, the assessment of the product will be based on the worst case conditions indicated by the leaching test studies.

5. In certain situations where a regulatory standard is not contravened, the DWI and its expert advisers may adopt a more conservative approach. This approach may reflect concerns that derivation of the standard did not take account of, e.g., more recent information on risks to health, or of other potential sources of exposure to the substance in question.

6. Toxicity data may be requested to allow evaluation of long-term health risks. In addition to the basic toxicity data requirements, this may include, but are not limited to, genotoxicity, carcinogenicity, full reproductive and developmental toxicity. The health risk assessment will ascertain whether an acceptable margin of safety exists between the potential daily human exposure and dose-response characteristics indicated by the toxicity data (e.g. No Observed Adverse Effect Level [NOAEL], Lowest Observed Adverse Effect Level [LOAEL] etc)

7. Toxicity data may be requested to allow evaluation of health risks. In addition to basic toxicity data requirements, this may include 90-day toxicity studies and studies of genotoxicity and reproductive toxicity. The health risk assessment will ascertain whether an acceptable margin of safety exists between the potential daily human exposure and dose-response characteristics obtained from the toxicity data (e.g. NOAEL, LOAEL etc) OK

Annex A – Pre-Application Testing & EEA Member State Testing

A.1 Introduction

Applicants sometimes wish to provide DWI with information on leachate studies undertaken on their product(s) because it is thought that this will speed up the application process. The DWI will consider results of equivalent product approval testing undertaken in other European Economic Area (EEA) Member States - see **A.3**. In all other instances it is advised that testing does not proceed until notified – see section **5.1**

A.2 Pre-Application Testing

Where applicants arrange for testing to be carried out before submitting their application, they should consider the following advice:

a. Testing should be undertaken by one of the designated test laboratories.
b. Test samples preparation and commissioning should be in accordance with the Instructions for Use and relevant for the use of the product with drinking water
c. Leachate preparation should be in accordance with BS EN 12873-1 for factory made products, except that pre-test disinfection of the test samples and testing of duplicate samples in each water type are not required
d. For site-applied products, sample preparation should be in accordance with BS EN 12873-2 for site applied products – note, that in this case there should be no break in the test sequence between completion of cure and commissioning and start of leachate preparation. Pre-test disinfection of the test samples and testing of duplicate samples in each water type are not required
e. Total Organic Carbon (TOC) and GC-MS general survey (GCMS) tests should be undertaken on each of the three 72 hour leachates, prepared in test water with and without the addition of 1 mg/l free-chlorine[4]. The results of these tests enable decisions regarding testing for specific target substances to be made.

Where applicants are aware of component ingredients which may represent a concern to health, they may also wish to commission, at their own risk, testing for the leaching of these compounds, on the clear understanding that further work may still be required

Generally the minimum testing requirements for particular product types are likely to include:

i. Polyethylene (PE) and PVC-U pipes – TOC and GCMS
ii. ABS – TOC, GCMS, styrene acrylonitrile (SAN) trimers and styrene
iii. Epoxy resins – TOC, GCMS, Bisphenol A, Bisphenol A Diglycidyl Ether (BADGE) and Epichlorohydrin

It is important to note that all pre-application testing is undertaken at the applicant's risk on the understanding that the DWI may request further or repeat testing based upon:

- the product formulation
- the results already submitted

Applicants are strongly advised to discuss any such testing with DWI's Regulation 31 Enquiries before they commit themselves to it.

[4] if the product is unsuitable for use in contact with chlorinated water, testing (in duplicate) using chlorine-free test water only will be acceptable.

A.3 EEA Member State Testing

Reports of equivalent testing undertaken under national approval schemes in other EEA States can be considered by the DWI provided any reports meet the following minimum requirements:

a) written in English (or certified translations)
b) are not test certificates, without detailed test conditions and results obtained
c) include a full description of the test samples, test sample curing (where appropriate), commissioning and test leachate preparation
d) include details of the analytical methods used, including limits of detection achieved and AQC data for the method(s), and the test laboratory accreditation, e.g. under EN ISO/IEC 17025
e) include actual results obtained, expressed as concentrations and/or migration rates with associated uncertainties

NOTE: reports based upon EN 12873-1 and 12873-2 normally meet these requirements.

Annex B – Evaluation of BS6920 Test Reports

B.1 Introduction

When the Drinking Water Inspectorate (DWI) considers applications for approval of products under regulation 31 of the Water Supply (Water Quality) Regulations 2016, it normally expects to see evidence of satisfactory results in the BS 6920 Tests of Effect on water quality (BS 6920 – parts 1 and 2).

Notes:
1. Passing these tests is a requirement for listing by the Water Regulations Advisory Scheme (WRAS) that deals with materials and fittings used within premises under the Water Supply (Water Fittings) Regulations 1999.

2. Approvals by the Water Regulations Advisory Scheme (WRAS) are subject to a five-year audit review process. WRAS approved products and BS 6920 test reports within 6 months of the end of this five-year period will not be acceptable in support of approval applications under regulation 31.

The following guidance sets out the approach to such reports.

B.2 WRAS Accredited Test Laboratories & their Reports

B.2.1 Competency of the test laboratory

Each WRAS accredited test laboratory for the BS 6920 Tests of Effect on Water Quality has been assessed against the requirements of BS EN ISO/IEC 17025 by UKAS, and their accreditation includes the BS 6920 tests in their current Schedule of Accreditation.

B.2.2 Test Reports

Usually the reports originating from the WRAS designated test laboratories are acceptable concerning:

a) Test sample descriptions and/or methods of sample preparation
b) Testing of additional test samples
c) Deviations from the published methods
d) The lack of explanations concerning suspect results and/or the decision to test additional samples

However, some reports may lack essential details that DWI needs in order to assess the results as part of its consideration of approval of a product under regulation 31(4)(a).

The following sections outline the DWI needs.

Test sample description

Sufficient detail must be provided to give assurance that it exactly matches the description of the product in question, including any reference names and reference numbers

i. The material description must include full details of the grade and supplier of the material used to make the samples tested.
ii. In this context sample reference to generic types of rubber, e.g. “EPDM rubber 70ºShore” is not acceptable – the actual grade used and name of the supplier/manufacturer of the rubber must be included as part of the sample description in the report.

If touch-up kits are to be supplied for on-site use in conjunction with factory applied linings/coatings of the same formulation, the BS 6920 tests (or equivalent) should have been carried out on plates that included an area coated by the test laboratory using the touch-up kit.

Test sample preparation - Site applied products

i. To be confident that the test samples for site applied products were made and cured in accordance with the Instructions for Use, the report must contain sufficient detail concerning test sample preparation and curing, plus any pre-commissioning/testing conditions. As a minimum the report should include the following details:

   a. who prepared the test samples
   b. if this was undertaken by the applicant, where the preparation was undertaken geographically and whether it was under the supervision of the test laboratory for multipart products, the mix ratio(s) used for each coat – see point "f)" below concerning multilayered products
   c. for each coat the duration and temperature of curing
   d. where the product was prepared away from the test laboratory, the time and conditions of storage during transportation to the test laboratory
   e. for multilayered products, e.g. the water contact top coat applied over an undercoat with or without an additional primer coat, details, as set out above, for each coat

ii. The temperature used during the curing period must be the minimum curing temperature specified in the Instructions for Use – this information must be included in the final report.

Test sample rinsing

This must have been carried out in accordance with the rinsing (and commissioning) instructions given in the Instructions for Use document.

Plastics pipes

The odour and flavour test (BS 6920-2.2.2) must have been undertaken on lengths of pipes including appropriate mechanical or welded joints. If this has not been carried out an odour and flavour retest, using appropriately jointed pipe lengths will be required.

Extraction of metals test (BS 6920-2.6)

Most reports will not contain the method and AQC details required by clause 10.1 of this standard. However, as this information is already available to DWI, the absence of this information in a test report is not a cause for concern.

Summary

If the test report fails to conform to any of these requirements, then further information will be required before the report can be accepted as suitable evidence to support the application. Therefore applicants, and their consultants (if used), should check reports before submitting them to DWI. Where deficiencies are noted, appropriate clarification should be obtained before submitting the report.

NOTE: Test Certificates or statements of approval cannot be used in support of an application in the absence of supporting full laboratory test reports.

B.3 Test Criteria

Guidance on the test criteria, interpretation of test results and checking of test reports is given in Section B.4.

Section B.5 contains some general comments relating to thermosetting materials, including most traditional rubber compounds, polyurethane materials (moulded and coating materials), thermosetting plastics (including glass reinforced polyester) and epoxy resins.

B.4 BS 6920 Test Criteria

B.4.1 Introduction

The following criteria are used to decide whether the results from BS 6920 Part 2 tests, show that the test material conforms to the test requirements of BS 6920 Part 1. In addition the various sections of Part 2 of BS 6920 include requirements for control and reference samples – these are given in *italic font* in the following text.

B.4.2 Odour and Flavour of Water Test (BS 6920-2.2)

Basic requirement

The requirement for this test (Clause 4 of BS 6920-1: 2000) (using both chlorine-free or chlorinated (1mg/l) water) are that:

i. The undiluted final extracts from the test material/product must be free from odour
ii. Two of the three test panellists must report that the first 1:1 dilutions of the final extracts obtained from the test material/product are free from flavour and no flavour is reported by any panellist in the second 1:1 dilutions of the final extracts.

Note: even if a material/product will not be in contact with chlorinated water, it is a normal requirement that this odour and flavour test is carried out using both water types, since compounds leaching from the product into water could react with chlorine when the water is subsequently chlorinated. The only exception to this requirement is for materials and products used up-stream of a reverse osmosis membrane.

Permitted re-testing

If an odour is detected in the undiluted final extracts by two or more panellists, and/or a flavour is detected in the first dilution of the final extracts by two or more panellists, then the product fails to meet this test criterion, *unless* two further sets of test samples are assessed and the results for both additional sets of samples meet the requirements as set out in “a i” and “a ii” above.

Test validation

The test is deemed to be invalid if a flavour is detected in the 1st dilution of the blank, with or without the addition of chlorine.

B.4.3 Appearance of Water Test (BS 6920-2.3)

Basic requirement
Any increase in the colour and turbidity of the final (i.e. seventh) extract from the material/product must be less than 5 Hazen units and 0.5 FTU respectively (when compared with the reagent blank/test water).

Permitted retesting
If any colour or turbidity is detected in the final extract the product fails to meet the test criteria, *unless* two further samples are tested and the means of the colour and turbidity results for *all* of the samples meet the test criteria

B.4.4 Growth of Aquatic Microorganisms (BS 6920-2.4)

Basic requirement
The mean dissolved oxygen difference between the water in contact with the test material/product and the negative control system must be less than 2.4 mg/L. (See Notes 1 and 2 below).

Permitted re-testing
If the material/product gives a mean dissolved oxygen difference (MDOD) value in the range 1.7 to 2.9 mg/L, then two further samples of it must be tested. If further testing is required, the arithmetic mean of the three dissolved oxygen differences must be less than 2.4 mg/L for the material/product to conform with the requirements.

Notes.
1. The mean dissolved oxygen difference (MDOD) value obtained for the material/product is a measure of the ability of your product to support the growth of microorganisms - as the growth of the microorganisms increases oxygen is removed from the test system and this loss is compared with the control system. Thus the greater the loss of dissolved oxygen from the water in contact with the material/product, the greater the MDOD value.
2. An additional reference system is included for all cementitious products - if this system gives an MDOD that is 0.5 mg/l greater than the MDOD for the positive reference test (Paraffin Wax), the product is reported as showing a bacteriostatic/bactericidal effect, and does not conform with the test requirements.

Test validation
*The test is invalid if any of the following criteria are **not** met –*
1. *Glass reference container – the MDOD value shall be (0.0±0.6) mg/l*
2. *Wax reference container – the MDOD value shall be (7.5±2.5) mg/l*
3. *The control container shall have a mean dissolved oxygen concentration of (8.5±2.5) mg/l*

B.4.5 The Extraction of Substances that may be of Concern to Public Health (Cytotoxicity) Test (BS 6920-2.5)

Basic requirement
If the first aqueous extract from the material/product is free from toxicity to the test cell line, it can be regarded as suitable for use in contact with potable water in relation to this particular test.

Permitted re-testing
If any toxicity is detected in this extract, then the material/product fails to meet the test criteria, *unless* two further samples are tested and found to be free from any toxic response.

Test validation
The test is invalid if the following criteria are not met:

1. *All blank tubes shall show healthy confluent growth of the cell line*
2. All zinc sulphate solution tubes shall show cell rounding and death.

B.4.6 The Extraction of Metals Test (BS 6920-2.6)

Basic requirement
Any metal present in the final duplicate extracts obtained from the material/product must be at levels less than the prescribed concentrations and values (standards) set out in the "The Water Supply (Water Quality) Regulations 2016: (Statutory Instrument 2016 No. 614).

Permitted re-testing
If the standards of any metal is exceeded in either of the final extracts from the test material/product then it fails to meet approval requirements, *unless* three further samples of the product are tested and the levels of the specified metals in the extracts (from all additional samples) do not exceed the standards.

Note – in the case of cementitious products it is common to find aluminium concentrations in leachates in excess of the 200µg l^{-1} requirement; such a failure has to be considered in the light of the very aggressive test water used for this test as part of an assessment of how the product will be used in-service, including the water types for which the product is suitable – usually specified in the Instructions for Use document.

B.5 Assessing Test Reports for Thermosetting Products and Materials

B.5.1 Introduction
Thermoplastics materials, e.g. nylon, acetal, polyethylene, PVC-U etc., can be repeatedly melted (at elevated temperature) and then allowed to solidify, with minimal effect on their performance in both the BS 6920 tests of effect on water quality and upon general leaching characteristics, including the GCMS general survey.

However, for thermosetting materials, e.g. traditional rubber compounds, GRP products etc., the performance of products in both the BS 6920 tests and specific leachate studies may vary considerably, according to the method of manufacture and curing. Therefore it is important to note, that when assessing any relevant test reports for thermosetting materials/products, evidence will be required that the test samples were manufactured in an identical way to that to be used for the final product.

B.5.2 Products covered
For use in contact with drinking water, thermosetting materials/products usually fall into two distinct groups:

a) Thermosetting elastomers (traditional rubbers), e.g. nitrile, EPDM, butyl, silicone etc. – see B.5.3 below
b) Resin based products, including phenolic thermosetting resins, epoxy resins, glass reinforced polyester products and some polyurethanes.

B.5.3 Test samples

The samples used for test purposes must have been manufactured and prepared in an identical manner to the final products, including conditions such as:

a) Basic manufacturing technique, e.g. extrusion, moulding, calendaring, pultrusion etc.
b) Cure time and temperature
c) Post cure treatment, including how this was achieved, e.g. steam, hot air etc.
d) Dimensions of the final products

Although manufacturers may claim that the cure and post-cure conditions used for manufacturing the product may achieve the same **degree** of cure as the conditions used for preparing the test samples, e.g. a compression moulded compared to an extruded rubber seal, these are *different manufacturing processes.* The results obtained from these different processes will vary for both BS 6920/Water Regulations Advisory Scheme (WRAS) testing, and with specific leachate studies (including GCMS general surveys).

Explanatory note - effect of cure conditions on rubber compounds. The effect of cure conditions (duration and temperature) and method of manufacture can have a marked effect upon the performance of rubber compounds in both BS 6920 tests and leachate studies, with the greatest variability seen in the odour and flavour and growth of aquatic microorganisms tests. It is common for a rubber material to give different results in these tests on the basis of the manufacturing method, e.g. moulding, extrusion or calendaring. The magnitude of these effects will depend upon the nature of the rubber and upon the ingredients used, but generally the greater the cross-link density achieved within the cured rubber, the better the performance in the tests.

Annex C - Evaluation of test reports from non-designated test laboratories

C. 1 Introduction

When DWI considers applications for approval of products, it is able to take into account results of *testing* undertaken in other EEA states. Claims of conformity, listings in an approved list, and/or letters of acceptance by an EU Member State do not provide sufficient evidence for DWI – a full report in English (or a certified translation) is required giving full details of:

a) The product
b) Test sample preparations
c) Methods of test
d) Test results
e) Acceptance criteria

Unfortunately the various European Member State testing schemes do not have a consistent approach to:

- Test sample requirements
- Leachate preparation conditions
- Tests undertaken
- Analytical methods used
- Interpretation of the results, including acceptance criteria

This Annex provides guidance on the level of information required to enable DWI to consider the results of such testing from non-designated European test laboratories, together with advice on some non-EU test requirements – see Section C.4.

C.2 General Assessment Criteria

In assessing any report from non-designated DWI test laboratories for use in support of an application for approval under regulation 31[4], the following general criteria will be taken into account. If **any** of the following criteria have not been met, then it is likely that the reported test results will have little value to DWI when considering the final test requirements, or in agreeing the approval of the product. The criteria are as follows.

C.2.1 Competency of the test laboratory

The test laboratory must have been assessed for compliance with EN ISO/IEC 17025 by a third party for the tests reported, and the accreditation of the test laboratory shall have been valid at the time of testing and issue of the test report.

Note: in the UK this assessment would be undertaken by UKAS; similar arrangements exist in other countries.

C.2.2 Test method accreditation

The test laboratory schedule (scope) of accreditation under EN ISO/IEC 17025 must include the test(s) covered by the test report at both the time of testing and issue of the test report.

C.2.3 Test sample description and preparation

Sufficient detail must be provided in the test sample description (such as reference names and numbers) to demonstrate that the sample is from the same product for which the application is being made.

In the case of a **site applied product**, the report shall contain sufficient detail concerning test sample preparation and curing, plus any pre-commissioning/testing conditions, to be confident that the test samples were made and cured in accordance with the Instructions for Use of the product. The temperature used during the curing period is the minimum curing temperature, as specified in the Instructions for Use.

C.2.4 Test sample rinsing

This shall be conducted in accordance with the rinsing instructions given in the IFU document.

C.2.5 Surface area to volume (S/V) test ratio

This shall be clearly stated in the test report. If it is given, it shall be 150 cm^2/litre (15000mm^2/litre;) or greater for any of the following tests – odour and flavour; colour and turbidity; promotion of microbial growth; leaching of metals.

C.2.6 Test method(s)

Sufficient detail must be included on the method(s) used in terms of:

a) The outline of the method of analysis used
b) The limit(s) of detection (LoD) of the chosen method
c) The results of any control or spiked samples tested at the same time

C.2.7 Results

Full results shall be given. The criteria used to pass or fail the tests shall be given. Explanations shall be given for any failures or unusual/unexpected results.

C.2.8 Summary

If the test report fails to conform to any of these requirements, then further information will be required before the report can be accepted as suitable evidence in support of the application. Therefore applicants, and their consultants, should check test reports before submitting them to the DWI. Where deficiencies are noted appropriate clarification should be obtained **before** submitting the report.

Test Certificates or statements of approval cannot be used in support on an application in the absence of supporting full laboratory test reports.

C.3 BS 6920 Tests Of Effect on Water Quality

C.3.1 BS 6920 test reports from non WRAS accredited test laboratories

These are sometimes submitted in support of applications; where this is done an initial assessment of the report is made using the criteria set out in section C.2 of this Annex. In addition checks need to be carried out to ensure that:

a) The individual test results do indeed confirm that the test material/product has met the relevant test criteria, as set out in the current version of BS 6920-1.
b) The test results provided include all the relevant information required by the reporting/test report sections of the most recent versions of the appropriate individual sections of Part 2, BS 6920.

The test report will be deemed as unacceptable if any of the information specified for the relevant part of BS 6920 is not included- the missing information will need to be provided. If this information is not available, appropriate repeat testing will be required.

C.3.2 Equivalent testing

Regulation 31(3)(b) states that testing to the requirements of "an appropriate British Standard or some other national standard of an EEA State which provides an equivalent level of protection and performance" can be considered. If the results of tests are submitted which have been undertaken using national test methods and requirements of another EEA state, DWI will consider the full test reports provided that they:

a) Are in English (or a certified translation into English is submitted)
b) Include a full description of the test samples (how they were prepared, test sample curing – site applied products only), and full product identification.
c) Include full details of leachate preparation (surface area to volume ratios, extraction temperature, test water etc.)
d) Outline the methods/techniques used to analyse the leachates (including appropriate AQC data)
e) Give the tests results and the criteria for pass or fail

Important note: DWI cannot consider either Test Certificates or summary reports which do not include this information.

C.3.3 Plastic pipes (and their fittings)

Any odour and flavour assessment (BS 6920-2.2 or equivalent) undertaken on the pipes must have been carried out by filling test lengths of pipe incorporating appropriate joints (heat welds, solvent welds or mechanical couplings). If this has not been done, such testing will be required for the application to be considered.

C.4 Other Specific Standard Test Reports

The following guidance is provided to help in assessing any report in support of an application for approval under regulation 31. This guidance is based upon the following standards:

C.4.1 Australia & New Zealand Standard AS/NZ 4020 (generally equivalent to BS 6920)

Most of the test methods and requirements of this standard are based upon BS 6920. However, there are some important differences that have to be taken into account when assessing the suitability of such testing for UK purposes.

General differences

- Scaling Factors (clause 5 and Appendix B of AS/NZ 4020), whereby the test results can be related to proposed use by applying conversion factors to the results – these are not used in assessing materials for conformity with BS 6920
- Product Exposure (section A4 of AS/NZ 4020) – the preferred method of extract preparation is by filling the complete assembled fitting – in the case of BS 6920 testing individual materials are assessed on their own.
- The Metals Extraction Test for End-of Line Fittings (Appendix I of AS/NZ 4020) – there is no equivalent BS 6920 requirement to this.
- Test methods of AS/NZ 4020 are potentially applied to both metallic and non-metallic materials (***except*** that the tests for growth of aquatic microorganisms and genetic toxicity of substances that leach from products only apply to non-metallic materials and the extraction of metals test may not have been undertaken for non-metallic products)

Specific tests differences

- Taste of Water Extract (Appendix C of AS/NZ 4020) - selection and number of tasters in the taste panel, and the absence of the requirements for an odour assessment
- Growth of Aquatic Micro-organisms (Appendix E of AS/NZ 4020) – in addition to the MDOD value, this test includes specific bacterial counts
- Cytotoxicity of Substances that Leach from Products (Appendix F of AS/NZ 4020) – three sequential leachates are prepared and tested (in BS 6920-2.5:2000 this test is undertaken on the 1st 24 hour extract/leachate only)
- Genetic Toxicity of Substances that Leach from Products (Appendix G of AS/NZ 4020) – there is no equivalent BS 6920 requirement; this test is based upon the Ames test.
- The Extraction of Metals (Appendix H of AS/NZ 4020) - only 10 of the 12 metals specified in BS 6920 2.6, although test criteria are usually more demanding in AS 4020. In practice this test may not be undertaken if the metals are not present in the product formulation.

Summary

The full test report should be reviewed to confirm that –

a) Only one material was tested in the taste and growth of aquatic microorganisms tests
b) The results for the cytotoxicity test on the **first** extract were satisfactory
c) Scaling factors were not used to establish conformity with the test requirements
d) All control and reference results were satisfactory

Provided that all these are satisfactory, and confirm full conformity with the requirements of BS 6920, it should only be necessary to undertake the following tests:

- Odour and flavour test (BS 6920-2.2.1)
- Extraction of metals test (BS 6920-2.6) for any missing metals,

C.4.2 Singapore Standard SS 375 (partially equivalent to BS 6920)

Most of the test methods and requirements of this standard are based upon BS 6920. There are, however, some important variations that may need to be taken into account when assessing the suitability of such testing for UK purposes:

- An odour assessment may not have been undertaken
- The extraction of metals test has different maximum acceptable concentrations.

Summary

The full test report should be reviewed to confirm that testing and reporting is in accordance with the current BS 6920 test requirements, ensuring that all control and reference results are included and satisfactory. It is particularly important that an odour test has been undertaken. If the test report does not include all this information, additional testing using the current BS 6920 methods and requirements will be necessary.

C.4.3 American Standard ANSI/NSF 61

This national US standard includes a wide range of test requirements for non-metallic materials and fittings used in contact with drinking water. Its primary concern is with the leaching of chemical constituents, contaminants and impurities into drinking water.

In comparison with the WRAS/BS 6920 test requirements, ANSI/NSF 61 does not consider odour and flavour effects, or the potential of materials to promote the growth of microorganisms. Thus, it will be necessary, (as a minimum) to undertake these BS 6920 tests.

Results from leachate studies may be of help to DWI when considering the need for specific analysis requirements, provided that either the test report, or supporting information includes all appropriate details, as set out in section C2 of this Annex.

Reports that are deficient in any of the aspects covered in Section C are unsuitable for submission to support the application.

C.5 Assessing Test Reports for Thermosetting Products and Materials

See Annex B.5

Annex D – Die Away Leaching Study

D.1 Introduction

Results from leachate studies, undertaken at the request of DWI, may indicate the presence of specific compounds at concentrations that might be of concern to public health, and/or the presence of a number of unknown compounds at significant concentrations. After evaluation of the leachate study report by expert toxicologists, additional information may be required to show how long these compounds may continue to leach into water before falling to acceptable concentrations. In these circumstances a die-away study may be requested. The following guidelines are provided to help with the design of such a study.

D.2 Die-Away Study

Before a die-away study is started the test laboratory should submit to the DWI for comment, full details of the proposed test protocol, method of analysis, and the limits of detection (LoDs) achievable.

D.2.1 Test Protocol

Test samples should be prepared and cured, rinsed and then exposed to the test water(s) in an identical manner to those originally assessed. In all cases the first 72 hour leachate should be collected for extraction and analysis. Subsequent 72 hour leachates should be collected, and extracted where required, for possible subsequent analysis.

Thought needs to be given to how frequently the leachates taken should be analysed, and for how long the series of 72 hour leaching periods may need to be extended. Some indication on this may be obtained through a preliminary investigation analysing leachates for total organic carbon, or other suitable and appropriate indicator, for each 72 hour leachate from an extended series of leachates. In the case of specific determinands, some of which may not have been specified originally, the chosen analytical method should normally have a limit of detection in the region of 1 to 5µg/l; in the case of a few determinands however, this may not be achievable and advice from DWI should be sought.

D.2.2 Reporting

Once the study has been completed, a short report should be submitted electronically to the DWI, including the following information:

a) detailed description of how the test leachates were prepared, e.g. temperature, free-chlorine concentration, etc.
b) the detection limits achievable for the chosen method
c) test results and AQC data
d) the die-away results presented as a graph

Note: if the concentration of the compound(s) of interest is ≤1µg litre^{-1} during the die-away study, or the leaching rate has reached equilibrium, then this information should be presented as a linear:linear graph.If this low concentration is not achieved and the leaching rate has not reached equilibrium, the use of other graphical presentations, such as log:linear or log:log may help in estimating the possible decay of the compound(s) of interest.

IMPORTANT NOTE: Applicants should not arrange for any die-away studies to be started until agreement on the proposed test protocol has been received from the DWI.