Feasibility of a UK Positive List for Polyethylene Pipes in contact with drinking water supplies

Draft Final Report to the Department of the Environment

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FEASIBILITY OF A UK POSITIVE LIST FOR POLYETHYLENE PIPES IN CONTACT WITH DRINKING WATER SUPPLIES

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The feasibility of adopting a 'Positive List' approval system for polyethylene (PE) pipes in contact with public drinking water supplies has been investigated.

The current Dutch and UK approval arrangements for PE products for use in contact with drinking water were assessed. The main issues which would need to be considered in relation to the use of the Dutch PE positive list in the UK were identified.

The issues concern an acceptance of the toxicological basis on which the positive list would be established, other measures of protection of consumers' health (including the determination of 'overall' migration, general survey GCMS analysis, quality control and audits), the incorporation of the Dutch positive list into UK documentation, and the identification of bodies who would assess and approve products under the system.

The views of the manufacturers of PE pipes were sought, and a meeting was held to discuss the issues with the British Plastics Federation (BPF). Concerns were raised by BPF about the possible unfairness of introducing a faster approval system for PE products than would be available for other products.

The potential advantages (a simple and transparent system for processing applications) of a system based on positive lists for approving PE pipes, and possibly other products, must be weighed against the disadvantages (the complexities and costs of initially establishing and implementing such a system). On balance, no strong case for change was identified, although the considered views of manufacturers are awaited.
### CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXECUTIVE SUMMARY</td>
<td>i</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>iii</td>
</tr>
<tr>
<td>1. INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>1.1 Background</td>
<td>1</td>
</tr>
<tr>
<td>1.2 Objectives</td>
<td>2</td>
</tr>
<tr>
<td>2. ASSESSMENT OF THE DUTCH POSITIVE LIST SYSTEM FOR</td>
<td>3</td>
</tr>
<tr>
<td>POLYETHYLENE</td>
<td></td>
</tr>
<tr>
<td>2.1 Notes on the application of the Dutch PL system</td>
<td>3</td>
</tr>
<tr>
<td>2.2 Issues arising from application of a PL system</td>
<td>7</td>
</tr>
<tr>
<td>3. CONSULTATION WITH MANUFACTURERS</td>
<td>11</td>
</tr>
<tr>
<td>4. CONCLUSIONS</td>
<td>13</td>
</tr>
<tr>
<td>5. RECOMMENDATIONS</td>
<td>15</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>17</td>
</tr>
</tbody>
</table>

### LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 2.1</td>
<td>Committee/certification structure</td>
<td>4</td>
</tr>
<tr>
<td>Figure 2.2</td>
<td>Process for seeking approval</td>
<td>6</td>
</tr>
<tr>
<td>Figure 2.3</td>
<td>Toxicity assessment of substances</td>
<td>8</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

1.1 Background

1.1.1 Interest of the Drinking Water Inspectorate in positive lists

The DWI represents the Department of the Environment (DoE) on CEN Technical Committee 164, Working Group 3 (TC164 WG3), the group responsible for developing tests to assess the effects of construction products on drinking water quality. The DWI also provides the chairman and secretariat to the Committee on Chemicals and Materials of Construction for use in Public Water Supply and Swimming Pools (CCM), which advises the Secretary of State on the approval of water supply products under Regulation 25(1)(a) of the Water Supply (Water Quality) Regulations 1989.

Participation in CEN meetings has revealed that certain practices in other European countries appear to offer advantages over the UK approval system. Specifically, the use of positive list (PL) systems for approving the use of some polymeric materials may lead to quicker and simpler processing of applications for approval.

The Drinking Water Inspectorate (DWI) is considering the feasibility of establishing a PL system in the UK for PE pipes, perhaps similar to the PL system in the Netherlands.

1.1.2 Principles of a Positive List system

A PL, in this context, is a listing of permitted chemicals that can be utilised for the production of a product to be used in contact with drinking water. Chemicals that feature in a PL usually have received a thorough examination by the relevant authorities. The chemicals are assessed for their potential to cause adverse effects on the health of consumers of drinking water that has been in contact with the product.

There are two main advantages of a PL system of approving materials over systems based on individual assessments:

- manufacturers have a clearer idea of chemicals that are likely to be acceptable to regulators; and
- because all the toxicological assessments have been already carried out, it leads to quicker approvals if the product contains only the permitted chemicals.

A PL may specify the materials covered by the list and the chemicals that are safe to use in the material, provided specified limits are met on their levels; either in the finished product or leaching from the product into water. Usually, PLs relate to organic materials. The Dutch PL is applicable to basic materials, such as polyethylene (PE) and rubbers. A
list can be exclusive (that is, manufacturers can only use chemicals that are on the list) or non-exclusive, (that is, products that include chemicals not on the PL can be assessed on a case-by-case basis). The Dutch PL is non-exclusive.

1.2 Objectives

The objectives, as specified by the DWI, were as follows:

i) to consider the Dutch and UK approval arrangements for PE pipes and to advise whether the Dutch PL system offers advantages in terms of faster determination of applications for approval, reduced costs to applicants or reduced costs in administration of the approval system;

ii) to consult UK approval holders, PE granule and pipe manufacturers and water industry representatives to obtain their views on the feasibility of introducing a UK PL system for PE pipes;

iii) to consult BSI to establish whether the PL approach might be given effect in a new or revised British standard;

iv) to formulate technical and administrative requirements, a timetable for implementation and estimates of the cost of introducing and implementing the system.
2. ASSESSMENT OF THE DUTCH POSITIVE LIST SYSTEM FOR POLYETHYLENE

2.1 Notes on the application of the Dutch PL system

As a part of this contract, details on the Dutch PL system and its practical application in authorising the use of polymeric products in contact with drinking water were gathered. The practical details of the operation of the system in The Netherlands were discussed with Dutch officials. This information is summarised in a report, produced under this contract (DWI 4077, 1996).

The Dutch approval system and the associated PLs are explained in the following documents:

1. KIWA Regulations: 1 January 1994
2. Guideline quality of materials and chemicals for drinking water supplies: 1994

The following notes attempt to clarify, on the basis of information provided during the discussions, salient aspects of the scheme described in these documents.

Figure 2.1 gives the structure of the Dutch scheme in terms of the basic committees and reporting paths. The scheme is voluntary. The CGCMD reports to the Chief Inspector who communicates with nine regional inspectors who control the corresponding Drinking Water Supply Companies. It meets roughly twice a year and its membership includes:

- VROM
- Ministry of Health (Drinking Water)
- KIWA
- RIVM
- VEWIN

Much of its work is done by correspondence.

Reporting to CGCMD is its sub-committee on toxicology, known also as W4. This committee seems to do most of the work on assessments that KIWA is not authorised to handle on its own. It meets when necessary which is usually about six to seven times each year. Membership includes representatives of:

- KIWA
- RIVM
- VEWIN
- Manufacturing industry (as an expert on plastics technology who helps to blend theory with practice)
Figure 2.1  Committee/certification structure
RIVM plays a major role in addition to membership. W4 has some links with another ‘sister’ committee that deals with packaging materials.

Most of the resourcing for these committees, and any RIVM additional activity, is funded by government. W4 has at least 50% government funding, the rest being from the manufacturing and water industry.

KIWA reports to W4 either to inform, in the case of ATA’s awarded, or for guidance or a toxicological evaluation on a chemical or material.

KIWA undertakes pre-certification evaluations of the product manufacture. This involves inspection of production processes (mainly ISO 9000 compliance) and the taking of samples. These samples appear to be analysed for:

- Composition (agreement with manufacturers’ declaration);
- Leaching of components (agreement with PL requirements or requirements established on an ‘individual assessment’ basis);
- Fingerprint using IR, thermal analysis or similar technique.

Similar sampling/testing is undertaken post certification at specified intervals.

Figure 2.2 indicates the flow of information and decisions to be made. At the heart of this is the contract/agreement set up between KIWA and the manufacturer. In practice a manufacturer would seek an ATA first to ensure the product is ‘safe’. Then a product certificate would be sought which covers performance requirements This and the ATA and other product and manufacturing details form the contract/agreement. In this agreement the purity of additives (including those on the PL) may be agreed. It is possible that different agreements on purity for the same chemical could be reached on products from different manufacturers.

In principle, there is nothing to prevent the manufacturer providing data on leaching in relation to chemicals that appear on a positive list. There is no ‘approved’ list of test laboratories.

If the product contains only substances on the PL, then KIWA can handle the approval process itself, unless there is some other potential issue. For example, there may be some evidence of chronic leaching of ‘less-toxic’ substances such as ‘metals or exfoliation of linings’. In such cases they would then seek guidance from W4. The Guidelines contain several statements that are included to allow some flexibility in the assessment so that the CGCMD is not automatically compelled to give approval to a product if the basic requirements of the PL are met.

If the product contains a chemical (additive etc.) that does not appear on the appropriate material PL, or there is no PL for the material, then KIWA will inform W4 that an individual assessment is required. This may eventually lead to W4 recommending to CGCMD that the chemical is added to the relevant PL or that a new PL for the material involved is developed. The latter would not be undertaken for a single or minor product.
Figure 2.2  Process for seeking approval
GCMS is not used for a general scan for unsuspected chemicals in materials/products. It may be used for quantitative analysis of known substances.

In principle, if a chemical in a product appears in a PL for a different material, this does not enable it to avoid toxicological assessment by W4, although it seems to depend on the case in question. W4 may deviate from this if the materials are not too dissimilar, e.g. if both are polyolefins. In principle, the scheme covers cementitious products, with a modified test procedure.

Figure 2.3 indicates the derivation procedure for adding a substance to the PL. Much use is made by W4 of the Dutch PL for packaging materials. This list is consistent with the EC lists in terms of the derivation of limits from toxicity data. In the PL for materials in contact with drinking water, some chemicals do not have specific maximum tolerable concentrations (MTCs) listed. In these cases the toxicity is such that the level of migration implied by a total or ‘overall’ migration limit of 3 mg l\(^{-1}\) is considered ‘safe’.

The PL MTCs imply the need for satisfactory methods of analysis, i.e. in relation to detection limits, accuracy and general performance. Some of the PL chemicals have methods (mainly developed and kept by KIWA). They are of varying performance depending on the technical difficulties involved. The Guidance asks for a method of analysis for chemicals on the PL. Although KIWA has published a few methods, there are no standard (e.g. NNI) methods for PL substances.

The literature on toxicity is scanned by RIVM to see if any assessments for chemicals on the PL need to be revised.

Some aspects of the testing are still unclear:

- taste and odour testing and the documents that require such tests;
- associated tests such as heavy metals, as mentioned in the KIWA literature;
- detail on pre-certification audit testing and annual check-testing.

Some aspects are possibly not written down anywhere and are dealt with by ‘negotiation’ with the producer during arriving at an ‘agreement’.

### 2.2 Issues arising from application of a PL system to the UK

Another report was produced (DWI 4078, 1996), which:

- described the main features of the Dutch PL itself;
- considered the options for introducing such a PL approach to the UK approval systems and their consequences;
- and listed issues where decisions will need to be made.
Figure 2.3  Toxicity assessment of substances
In the Netherlands, PLs are used as a part of a more comprehensive certification scheme, which includes pre-certification and regular post-certification audits of manufacturing sites and their quality control systems. The potential implications of introducing the Dutch PL for PE in the UK were assessed. A number of issues that need to be considered were identified, in particular the following:

- The relevance of the definition of PE given in the Dutch PL to products on the UK market should be confirmed with UK manufacturers.
- A decision would need to be made on whether any addition to or deletion from the Dutch list would have to be made for its use in the UK, e.g. the addition of pigments for blue PE pipe.
- Are the criteria of toxicological assessment to determine the maximum tolerable concentration (MTC) acceptable in the UK? Currently the Department of Health members of the CCM decide the acceptability of leaching from products on an individual, confidential basis.
- Should an MTC be set for chemicals listed in the Dutch PL, but for which no MTC is currently set?
- From the experience with leaching tests on PE in the UK, should any other contaminants be included in the list, such as products of degradation or chlorination?
- Conversion factors to be applied to the results of UK leaching tests would need to be set, so that consumer exposure to leaching substances could be estimated from the results of laboratory leaching tests.
- The determination of ‘overall migration’ is by a gravimetric method not used in the UK. Total organic carbon (TOC) determination could be used instead. Consequently a MTC for TOC would need to be established.
- The principles of using the general survey GCMS method (not a feature of the Dutch system, but an important safeguard in the UK system) and establishing criteria of compliance should be considered in relation to use of positive lists.
- How could the Dutch PL be incorporated into UK documentation? The options include a direct reference to the Dutch PL, a separate UK list based initially on the Dutch PL or by the inclusion of a PL in a British Standard.
- Should a new standard, incorporating a PL, be a new stand-alone standard to which other relevant standards could refer, changing the latter as appropriate? Alternatively, should the PL be a part of the BS6920 standard?
• Should the PL be a part of one or more product standards (e.g. black pipes/blue pipes)? It needs to be decided to which products the PL approach would apply (to public water supplies/ on consumers premises, to pipes only or any other products, e.g. tank linings or membranes or, possibly, fittings).

• Advantages and disadvantages of the different options need to be considered to arrive at an optimum balance between costs/time savings and the degree of protection of consumer health.

The decisions would need to be made by the DWI, with considerable input from the Department of Health (DoH). The DoH would have to decide on the acceptability of the MTCs of the Dutch PL or else set alternative criteria that would be published in the PL. If the latter course were adopted (i.e. the DoH set and published maximum acceptable levels for leaching of specified PE ingredients), the mechanism for setting acceptance criteria would need to reflect the confidential nature of the compositional and toxicological information that has been provided by current approval holders and their suppliers.
3. CONSULTATION WITH MANUFACTURERS

A meeting was held at the British Plastics Federation, London, on 15 February 1996, to obtain the view of plastics manufacturers on the feasibility and desirability of a PL system for approving PE pipes in contact with water. Among those in attendance were representatives of major manufacturers of granules and pipes of PE and other materials, and representatives of DWI and WRC.

The Dutch PL system was discussed as an example of the type of approach that might be followed. It was stressed that many of the details, including the acceptance criteria (MTCs) for leaching and how these would be set, for the UK system were not yet decided by the regulators (DWI and DoH).

Some of the issues raised during the meeting were as follows:

- the possible barriers to technical innovation that a PL would introduce, particularly if the list were exclusive;
- the problem of the current lack of pigments on the Dutch PL, if this is adopted directly;
- additional testing that would be required, e.g. for potential taste and odour problems;
- potential difficulty of the use of ‘generic’ substances, rather than the brand-name versions;
- the desirability of reductions in the cost and, especially, time to process applications;
- the need for a common level of testing for all materials, including traditional pipe materials;
- the desirability of harmonised European systems or mutual recognition arrangements.

At the meeting, three main concerns among the manufacturers’ representatives were identified:

1. A PL system might move more of the costs and responsibilities of testing products and gaining approval from the PE granule manufacturers to the pipe makers. Therefore the BPF, representing granule and pipe makers, may not be able to give a unified view on this issue.

2. The proposed system should not in any way change the status of products currently approved under Regulation 25, which have been through the detailed individual assessment.

3. The proposed change to the approval system should have a common implementation date for pipes constructed from all thermoplastics materials, so as not to provide PE with a perceived advantage over other materials in a quicker approval route.
Although not discussed in depth at the meeting, the third point raised could require a considerable body of work. The extension of the PL to materials other than PE would require a detailed assessment of the ingredients that are used in the other materials and many issues that have been considered in this report for PE would need to be addressed for the other materials. If it is proposed to establish a UK PL for at least PE, polypropylene, polybutylene and polyvinyl chloride materials with a common implementation date, then the cost and time implications would need to be considered.

It was concluded that there were important areas where the BPF would like to consult more widely with its members. Further consultation was suggested and accepted. The BPF agreed to inform the DWI of their views after this consultation. At the time of preparation of this report, no final view was available.

Overall it seemed at the meeting that the manufacturers remained to be convinced of the advantages to them of the proposed modification to the approval system. It is possible that the initial response of manufacturers to the general principle of the proposed change to a PL-based system may alter when a detailed proposal, including the numerical values of the MTCs and the exact mechanism for assessing products and resolving the issues of concern, is brought before them.
4. CONCLUSIONS

In principle the use of PLs to approve a well-established product such as PE pipe could offer a faster mechanism for processing applications for approval under Regulation 25(1)(a). However, it is likely that in practice a number of difficulties would be met in establishing and operating such a system.

The Dutch PL for PE operates within a system where more reliance is placed on product specifications, manufacturing site audits and quality control systems than in the current UK system. The Dutch system sets published acceptance criteria (MTCs) for leaching that offer the advantage of transparency of assessment. However, the MTCs require conversion factors, for using laboratory measurements to assess consumers' exposure to substances leaching from products. Conversion factors would need to be set for the UK, where usage of products may differ from the Dutch situation.

The manufacturers of PE pipes were consulted, to discuss the feasibility of establishing a PL system for PE pipes. A number of major issues and concerns were raised, with no decisive majority view in favour of a PL system.

Although the final views of the manufacturers were not available, it is possible to reach the interim conclusions that this consultancy project has found that:

- It would be feasible to establish a PL system for assessing and approving PE pipes in the UK, with potential advantages in shortening and simplifying the assessment procedure.

- However, the disadvantages are that the initial implementation of the system would be complex, requiring major inputs from the DoH and existing approval holders.

On balance, there does not seem to be a strong case for changing the current system.
5. RECOMMENDATIONS

The study indicated that the implementation of a PL-based system would be complicated and that overall there was no strong case for an immediate change to the existing system. However, the considered views of the manufacturers are awaited. If further action is considered desirable, then the following actions would be recommended:

a) The Department of Health should be consulted for their views on the implications for public health of changes to the approval system.

b) A well-defined proposal for change should be put to the manufacturers, so that the details and implications of the scheme could be assessed.

c) Accurate costings should be obtained for the proposed scheme when the details have been established.
REFERENCES


KIWA (1993) Regulations for the ATA (Assessment on Toxicological Aspects) Product Certificate. KIWA.

British Standard BS6920:1990 Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water.

British Standard BS3412:1976 Polyethylene materials for moulding and extrusion.