

THE 4MS GROUP

DEVELOPING the COMMON APPROACH

1 Basis for a Common Approach

1.1 The 4MS intend to adopt common, or directly comparable, practices for:

- The acceptance of the constituents used in materials in contact with drinking water
- The testing of materials
- The use of common test methods and setting acceptance levels
- The specification of tests to be applied to products
- Reviewing factory production control and setting audit testing requirements
- Assessing the capabilities of certification and testing bodies

1.2 The objective of the Common Approach is not to introduce a single assessment system that operates in exactly the same way in each country. It defines a suite of policies and practices that can be adopted within the existing national legal and institutional frameworks. The aim is to ensure that products are assessed consistently and with the same outcomes irrespective of where the work is carried out.

1.3 It is recognised that there will be a period of transition before the Common Approach can be completely implemented because:

- It will take a period of years before all elements of the assessment process can be fully defined.
- Individual countries will have different programmes and processes to make changes to their existing arrangements.

However, whilst full implementation will take time to achieve, the Common Approach is being developed as a series of modules capable of individual adoption. It should therefore be possible for mutual recognition to be achieved for elements within the overall assessment process e.g. a common test method and acceptance level. Whilst for some time this will fall short of mutual recognition of a full product approval, it will reduce duplication of some tests and assessments.

2. Access to Information

2.1 The 4MS are committed to openness in the way the Common Approach will be implemented. The reports and documents that give the detailed information on the development and implementation of the various policies and practices will be made publicly available when they are finalised by the 4MS. This web site has been created for this purpose

3. Acceptance of Constituents

A primary control will be the approval of the substances and materials that go to make up products in contact with drinking water. The exact nature of the requirements will differ according to the nature of the materials

3.1 Organic Materials

Three of the four MS have Positive Lists of organic substances that are approved for use in products in contact with drinking water. A Report "Positive Lists for Organic Materials – 4MS Common Approach" has been agreed in January 2012.

The three current MS lists are being consolidated into a Combined List that will detail all the substances currently approved. The aim is to review the details of this List to move within five years to a position of having a single List of fully evaluated substances that will be accepted in each of the 4MS.

In addition to the Positive List controls, some of the 4MS have systems for the recognition of proprietary materials that can be accepted with only limited further testing. Creating a Common Approach in this area poses particular problems, but is under active review.

The 4MS are also working on common test requirements for organic materials.

3.2 Metallic Materials

Procedures have been agreed for the testing and acceptance of the composition of metallic materials.

“Procedure for the Acceptance of Metallic Materials used for Products in Contact with Drinking Water”
 “Draft of Common Composition List”

3.3 Cementitious Materials

Development work is in hand to produce a report on the acceptance of these materials.

3.4 Other Materials

Review work is in hand.

4. Use of Common Test Methods and Acceptance Levels

4.1 The 4MS have committed themselves to adopt, when finalised, the test methods currently under development by CEN/TC164/WG3. They then aim to agree common acceptance levels for each test so that a compliant test result in one country will be accepted by the other three.

4.2 Representatives of the 4MS regulators are active members of WG3 and the 4MS have also been involved in making proposals on the Regulatory Guidance on test methods that has been passed to CEN by the European Commission.

5. Specification of Tests to be Applied to Products

5.1 The 4MS are collaborating with the Commission’s Expert Sub Group on the determination of the tests to be applied to products in contact with drinking water. The Expert Group is concerned to prepare guidance to CEN on the drafting of test requirements in harmonised products standards (hENs). Once approved, these hENs will specify all the tests on products which may be applicable throughout Europe to secure regulatory acceptance and lead to the CE Marking.

5.2 The 4MS have been investigating differences in testing practices in the four countries. What this has shown is not so much that the tests performed are different, but that the philosophies and practices that determine which tests are carried out are significantly different. Testing practices are also influenced by legal requirements, institutional arrangements and the roles played by regulators and certifiers, and these are quite different in the 4MS countries.

5.3 This has led the 4MS to conclude that it will be impossible in the foreseeable future to develop standard practices to be carried out in the same way in each country. What they will now be studying is how they can ensure that the practices which are in use give comparable levels of protection. If this can be assured, approvals given in one country can be accepted by the others without further testing (mutual recognition).

6. Widening the use of the Common Approach.

6.1 The 4MS are hopeful that their work will lead to a wider adoption of the Common Approach in Europe. This would obviously produce greater benefits in terms of reduced frequency of testing and consistent high standards of consumer protection. Their arrangements anticipate two means by which other MS may collaborate in this work:

- I. Full membership of the Group for MS committing themselves to adopt the Common Approach for their product assessment activities.
- II. Registered User status for those MS who wish to adopt some or all of the Common Practices, but who do not seek, or are ineligible for, full membership.

6.3 The 4MS Common Approach is being developed at the same time as practices across Europe are being reviewed with a view to “harmonisation” under the terms of the current Construction Products Directive and the future Construction Products Regulation. Representatives of the 4MS are actively engaged with the Commission and its Expert Groups in this work. In some instances the 4MS Common Approach will be incorporated into harmonised practices, but in other situations the 4MS will be bound by the provisions of the harmonised arrangements when they come into force.