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RÉPUBLIQUE FRANÇAISE
MINISTÈRE DU TRAVAIL, DE L'EMPLOI ET DE LA SANTÉ

Bundesministerium für Gesundheit

Ministerie van Infrastructuur en Milieu

defra Department for Environment Food and Rural Affairs

DECLARATION of INTENT

between
the competent authorities of France, Germany, the Netherlands and the United Kingdom

concerning
the approval of products in contact with drinking water (drinking water quality)

The Ministry of Work, Employment and Health of the French Republic, the Federal Ministry of Health of the Federal Republic of Germany, the Ministry of Infrastructure and Environment of the Kingdom of the Netherlands and the Department for Environment, Food and Rural Affairs of the United Kingdom,

hereinafter referred to as the Signatories;

- led by the importance of product approval in drinking water protection,
- led by the history of developments at the EU level,
- pursuant to the benefits of technical collaboration as specialist staffing levels come under pressure,
- guided by the desire to provide a more formal basis for the co-operative activity already taking place,
- taking into account the Drinking Water Directive (98/83/EC), the Construction Products Directive (89/106/EEC) and other product specific European legislation, and Regulation (EC) Nr. 764/2008, laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State;

declare their intention to establish a co-operation in the field of approval of products in contact with drinking water (drinking water quality) under the following guidelines

OBJECTIVES

1. The objectives of this Declaration of Intent are
    a. to establish convergence of the operations of the national approval systems with the intention of reducing, and if possible eliminating, duplicate testing and assessment in the countries represented by the Signatories,
    b. to promote the development and implementation of approval systems that provide high, uniform, levels of consumer protection,
    c. to promote the optimum use of regulatory and scientific resources, and
    d. to collaborate in supporting developments at the European level aimed at creating consistent practice in approval systems.

AREAS OF CO-OPERATION

1. The areas of co-operation under this Declaration will include, but are not limited to
    a. development of common principles and practices on which national approval systems will be intended to operate, leading to mutual recognition of individual national assessments,
    b. the common principles and practices will cover all aspects of the operation and control of product approval as elaborated in the Explanatory Note to this Declaration,
    c. the implementation of common elements of practice as they are agreed provide steps on the path to mutual recognition of full national approvals when they are eventually based on the complete set of common principles, and
    d. co-ordination of the inputs made by the Signatories to activities and discussions at the European level in the framework of legislation and guidance with respect to the impacts of products and substances on drinking water quality.

2. The adoption of individual elements of common practice need not be simultaneous in all countries represented by the Signatories.

3. The Signatories will implement this Declaration in accordance with their national competences. In areas where they have no regulatory competence, they will make every effort to promote its implementation.

4. The Signatories will communicate to each other any proposals adopted within their national systems for approval of products and substances in contact with drinking water.

JOINT WORKING ORGANISATION

1. In order to implement this Declaration, the Signatories will establish a Joint Management Committee.

2. Each Signatory will designate a permanent representative in the Joint Management Committee.

3. The tasks of the Joint Management Committee will include
    a. the implementation of the co-operation,
    b. the elaboration of common principles and practises ,

c. deciding on the yearly work programme that clearly states deliverables, tasks and time table,
d. monitoring and evaluation of the co-operation,
e. the monitoring and assessment of wider developments that may impact the collaborative process, and
f. The preparation of an annual report to be submitted to the Signatories.

4. To enable the Joint Management Committee to fulfil its function, the meetings of the Committee may also be attended by national experts.

5. In order to facilitate the activities under this Declaration, (ad hoc) working groups may be established. Their Mandate and Terms of Reference will be decided upon by the Joint Management Committee.

6. The Joint Management Committee will adopt its Rules of Procedure.

7. Within national financial constraints, the Signatories agree to seek financial resources (staff and/or other) for implementing the collaborative work as laid down in the joint work programme.

INVOLVEMENT OF OTHER ORGANISATIONS IN THE CO-OPERATION

1. Competent authorities of other European Member States and EFTA Member States may become a Signatory to this Declaration on the understanding that they accept the convergence and resourcing responsibilities.

2. It is accepted that other European Member States and EFTA Member States may adopt the common principles and practices without becoming Signatory to the Declaration. The Signatories will inform those countries of changes in common principles and practises

3. The Signatories will work with the services of the European Commission to achieve harmonisation of testing and approval of products in contact with drinking water within the European Union.

EXTERNAL COMMUNICATIONS

1. The primary responsibility for stakeholder communication remains at national level, subject to the responsibility to give consistent messages and to feed back on issues of common interest through the Joint Management Committee.

2. Where circumstances require countries represented by the Signatories to communicate as a group, each Signatory will approve the information to be published or be represented at meetings.

AMENDMENT, EVALUATION, DURATION AND SIGNATURE

1. This Declaration may be amended at any time by mutual consent of the Signatories.

2. This Declaration will be subject to a joint evaluation not later than 4 (four) years after its commencement.

3. In case the Declaration ceases to have effect on account of termination thereof, such termination will not prejudice the completion of existing joint activities.

4. Any Signatory may opt out of the Declaration without penalty, and the remaining Signatories then have the opportunity to confirm or vary their commitment to it.

5. This Declaration does not create any rights or obligations under either national, European and international law.

Signed in Paris, Bonn, The Hague and London, in the French, German, Dutch and English languages.

Ministère du Travail, de l'Emploi et de la Santé, République Française

Directeur Géneral de la Santé

Didier Houssin,
signed Paris, 23 December 2010

Bundesministerium für Gesundheit, Bundesrepublik Deutschland

Ministerialdirektorin

Karin Knufmann-Happe,
signed Berlin, 21 December 2010

Ministerie van Infrastructuur en Milieu, Koninkrijk der Nederlanden

Directeur-Generaal Milieubeheer

Bernard ter Haar,
signed The Hague, 17 November 2010

Department for Environment, Food and Rural Affairs, United Kingdom

Director, Water, Floods, Environmental Risk and Regulation

Sonia Phippard,
signed London, 28 January 2011

Explanatory Note

Background Common Approach

In 1998 work started on the design and development of a single European scheme for the assessment of products in contact with drinking water; the European Acceptance Scheme (EAS). This work was being carried out under the auspices of the European Commission (DG Enterprise), but in 2006 the Commission withdrew its support for the EAS. Work was to proceed on a more limited “harmonisation” project under the Construction Products Directive, but this would not achieve the aims of the EAS.

France, Germany, the Netherlands and the United Kingdom (the 4MS), who had deferred any development of their national schemes pending the introduction of the EAS, agreed in 2007 to pursue a common approach to the assessment of products in contact with drinking water. The intention is to achieve the aims of the EAS in their countries, and to collaborate on the improvement of the national schemes. In addition to the national activities, the 4MS work together to propose guidance to the Commission on the regulatory aspects of the harmonised and supporting standards required to implement the provisions of the Construction Products Directive.

Basis for a common approach

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 and the setting of acceptance levels
- The specification of tests to be applied to products
- Reviewing factory production control and for audit testing
- Assessing the capabilities of certification and testing bodies

Acceptance of Constituents

Lists will be prepared and maintained of constituents that will be accepted by each of the 4MS in materials used in contact with drinking water:

- Positive Lists for Organic Materials
- Composition Lists for Metallic Materials
- Approved Constituents Lists for Cementitious Materials
- Positive Lists of Organic Additives to Cementitious Materials
- Relevant Lists for Other Materials

Testing of Materials

Programmes will be agreed for the tests to be applied to the materials incorporated in products submitted for assessment covering:

- Organic materials
- Metallic materials
- Cementitious materials
- Other materials

Where relevant common test methods will be used, using European Standards when they exist.

Common acceptance criteria will be specified for each test.

Testing of Products

Test requirements will be set for products submitted for assessment, distinguishing:

- Single material products

- Assembled products
- Multi-layer products
- Site applied products

For single material products, consideration will be given to the creation of Lists of Approved Materials, and to the testing (if any) to be applied to such materials when used in products.

For assembled products, common practice will be set for the further testing (if any) to be applied to product components that have previously been approved as separate products.

For each product type common practices will be set for sample selection.

A common schedule will be prepared of Conversion Factors to be used –when appropriate - in the interpretation of test results.

Production Control

Common requirements will be set for the factory production controls to be put in place by manufacturers.

Common systems will be used for the pre-certificate audit of FPC, for post- certificate surveillance, for periodic audit testing of products and for re-testing.

Certification and Testing Bodies

Common requirements will be set governing the competence of certification and testing bodies.

Organisation

The organisation of the work under this Declaration of Intent will be guided by the following principles:

a. There is no intention to change the primary role of the national drinking water regulators in the operation of their national systems.
b. No central organisation will be created to develop and introduce changes to national approval systems.
c. All development work and collaborative operational activity will be carried out by drawing on the resources and organisations that exist at the national level under the direction and co-ordination of the Joint Management Committee.
d. The resources provided from the national level will be directed into working teams (as Sub-Groups of the JMC) for either specific development projects or for ongoing co-operation, e.g. in the setting up and management of PLs, CLs and ACLs.

Costs and Benefits

Cost for national regulators

Costs will arise for the national water regulators from the allocation of their own resources to the collaborative work, and from expenses incurred for the services of specialist organisations and individuals. Costs incurred on development projects will normally be additional to those required for ongoing operations, but the extent of the provision made for development work remains a matter for national determination. It is anticipated that costs incurred in developing and enhancing approval systems using the pooling of expert resources will be less than would have been the case if each State had undertaken similar work individually.

Modest additional costs will arise from the attendance at meetings of the JMC and its Sub-Groups.

Benefits for national regulators

Benefits are anticipated from the pooling of specialist resources, the sharing of a wider range of experience and the peer review of proposals and ideas. These should lead to the highest and best value standards of practices being adopted. It will also be possible to demonstrate at the national level that the protection offered by the revised approval system has been benchmarked to best European practice.

Experience can be shared so that any issue arising from the operation of systems can be resolved and adopted by all. New regulatory challenges posed to one MS can be responded to from a wider pool of resources and with greater authority.
It should also be possible to monitor the performance of certification and testing bodies by using comparative data for a wider range of institutions fulfilling similar functions.

Third party benefits

Whilst the aim is to create net benefits for the national Regulators, there will be substantial benefits for industry. Manufacturers and suppliers will no longer need to track the differing requirements of the 4MS, and the costs currently incurred in repeating tests and compliance assessment processes in four different countries should be much reduced. At the end it will therefore also lead to a cost reduction for the consumer while keeping a high and uniform protection level.