

Anima Confindustria: "Materiali a contatto con acqua potabile e nuova Drinking Water Directive: a che punto siamo?"

**Materials and products in contact with drinking water:
state of play at national and EU level**



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Legislation currently in force in Italy: D.M. 174/2004

Scope:

Materials and products to be used in caption, treatment and distribution of DW
To be applied only to new installations or in case of maintenance

In force since:

17 July 2007

Jurisdiction:

Ministry of Health, Ministry of Ecological Transition, Ministry of Economic Growth

Positive lists for materials made of:

metals and alloys (Annex I); fibres, hydraulic binders, enamels, ceramics and glasses (Annex II); plastics and rubbers (Annex III with a reference to FCM legislation)

D.M. 174/2004: manufacture's duties

General duties:

- Internal controls and investigations
- Documents and data keeping
- Appropriate batch labelling and conformity declaration
- Contamination prevention during transport and storage

No application must be sent to MoH for materials in the positive lists

In case of a new material:

- MoH and ISS assess a dossier issued by the manufacturer
- The assessment is submitted to the IT Health Board for a final scientific opinion

D.M. 174/2004: info required for new materials

New materials NOT IN USE in the UE:

General info: applicant and object identification; composition; usage description; risks for the environment; possible authorizations granted by non-EU countries

Physico-chemical info: name, structure and purity of the components; analytical methods; results of migration tests

Toxicological info: known effects on humans; results of 3 genotoxicity tests, mutagenic tests on bacteria; mutagenic tests on mammalian cells; oral toxicity after 90 days; further tests required by the MoH

New materials IN USE in the UE:

General info: applicant and object identification; composition

Physico-chemical info: name, structure and purity of the components; analytical methods; results of migration tests

Administrative info: scientific opinion of the MS health board; applied toxicological procedure; official acts issued by the MS

D.M. 174/2004: migration tests

Mandatory for stainless steels, glasses, enamels, plastics, rubbers and new materials out of the positive lists

ISS & MoH do not perform analyses or tests; manufacturers are completely responsible for them

Test conditions:

- Demineralized water or acetic acid 4% as test water depending on test material
- Static contact for 24 h at 40°C, unless specified differently
- S/V as close as possible to the real use of the product or, otherwise, 0.5 - 2.0 dm⁻¹

D.M. 174/2004: limits and drawbacks

Concerning positive lists:

- Only a number of materials are ruled
- No specific rules for chemical reagents and filtration/treatment media
- Annexes containing positive lists expired in July 2012 (never updated)
- Fragmentation of Reference Legislation (FCM and DW)

Concerning test methods:

- Test methods are not based on existing applicable EN standards
- No organoleptic testing, general hygiene assessments (TOC, surface residues), evaluation of microbial growth potential

Concerning materials approval:

- Products/substances authorized by another MS needs to be assessed prior to be authorized
- No lists of approved materials/products available
- No third-party certification

Revision of the Italian legislation on CPDWs

In 2017, a review process was initiated involving the following stakeholders:

water utilities, producers' associations (e.g., Confindustria), the Italian accreditation body (Accredia), certification bodies, testing laboratories, experts from universities

Field of application:

all objects, chemical reagents, filtration and treatment media between water source and tap

Based on:

- the 4MS approach (currently replaced by ECHA's approach)
- UNI-EN standards for reagents and treatment media
- EU Regulation 528/12 + UNI-EN standards for biocides
- a process involving MoH, ISS, few accredited Certification Bodies, a number of accredited Test Laboratories

Attestation of Conformity System: 1+

(initial type testing; initial inspection of factory production control system; continuous surveillance, assessment and approval of FPC; audit testing of samples)

Recent changes in the national revision process after Dir. (EU) 2020/2184 entered into force

Art. 11 of the recast DWD states:

- ... COM shall adopt IAs to establish the specific min hygiene requirements for materials that come into contact with DW on the basis of the principles set out in Annex V (p. 2)
- COM shall adopt DAs ... by determining the appropriate conformity assessment procedure applicable to products covered by this Art. (p. 8)
- Pending the adoption of IAs referred to in p. 2, MSs shall be entitled to maintain or adopt national measures on specific min hygiene requirements for the materials ... (p. 9)
- COM shall request one or several EU standardisation organisations to draft a EU standard for uniform testing and assessment of products in contact with DW (p. 10)
- COM shall adopt DAs ... by establishing harmonised specifications for a conspicuous, clearly legible and indelible marking to be used to indicate that products in contact with DW are in conformity with this Art. ... (p. 11)

Waiting for new IAs and DAs:

- the process of revising D.M. 174/2004 has been suspended
- the validity of the D.M. 174/2004 has been extended
- the experience so far gained has been made available to ECHA

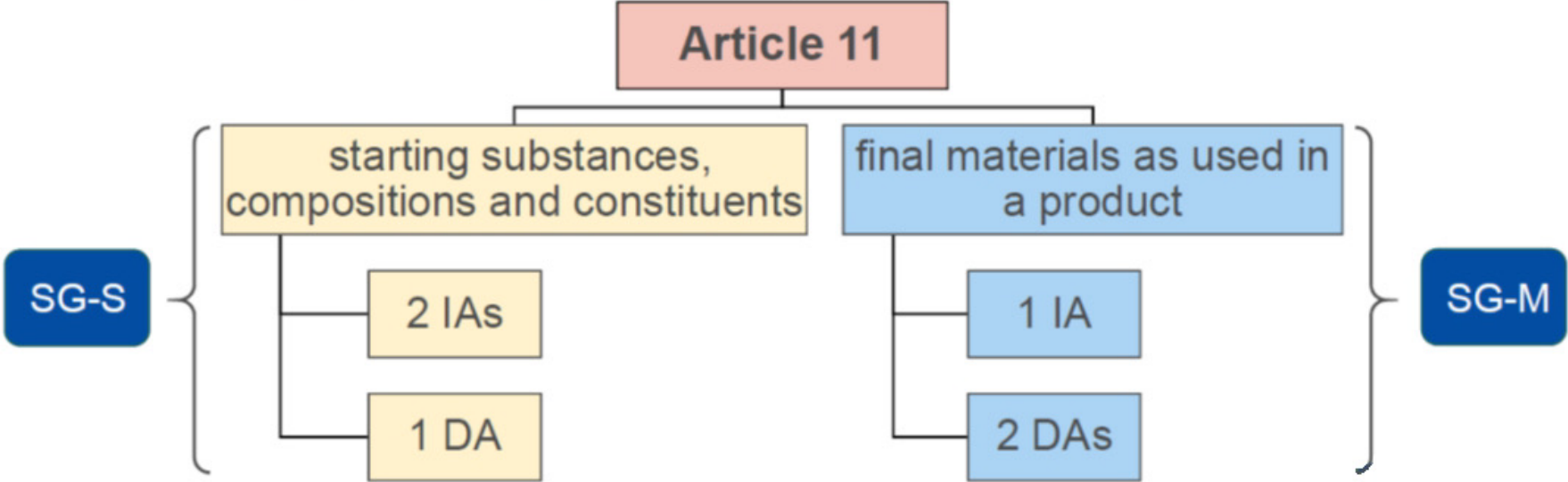
Implementing vs. delegated acts








Implementing and delegated acts called by the DWD

Directive Article 11:

Minimum hygiene requirements for materials that come into contact with water intended for human consumption



«Materials» vs. «Final materials» vs. «Products»





Material	Product
 <p>Plastic granules</p> <p>© Par Vacancylam - stock.adobe.com</p>	<p>Plastic pipe</p>  <p>© Par Alexey - stock.adobe.com</p>
 <p>Rubber granules</p> <p>© Par Laruboznikova - stock.adobe.com</p>	<p>Ring rubber gasket</p>  <p>© Par Coprid - stock.adobe.com</p>
 <p>Glue for PVC</p> <p>© Thedoral - stock.adobe.com</p>	<p>PVC pipe connectors</p>  <p>© Par NorGal - stock.adobe.com</p>

ORGANICS

Material	Product
 <p>Rolled steel sheet</p> <p>© Par Benjamin Saizaz - stock.adobe.com</p>	<p>Steel pipe</p>  <p>© Par Miron - stock.adobe.com</p>
 <p>Rods of brass</p> <p>© Par Avaleisu - stock.adobe.com</p>	<p>Brass valve</p>  <p>© Par Altwart - stock.adobe.com</p>
 <p>Copper alloy rods</p> <p>© Par Amerod - stock.adobe.com</p>	<p>Fittings</p>  <p>© Par Kos 1975 - stock.adobe.com</p>

METALS

«Materials» vs. «Final materials» vs. «Products»

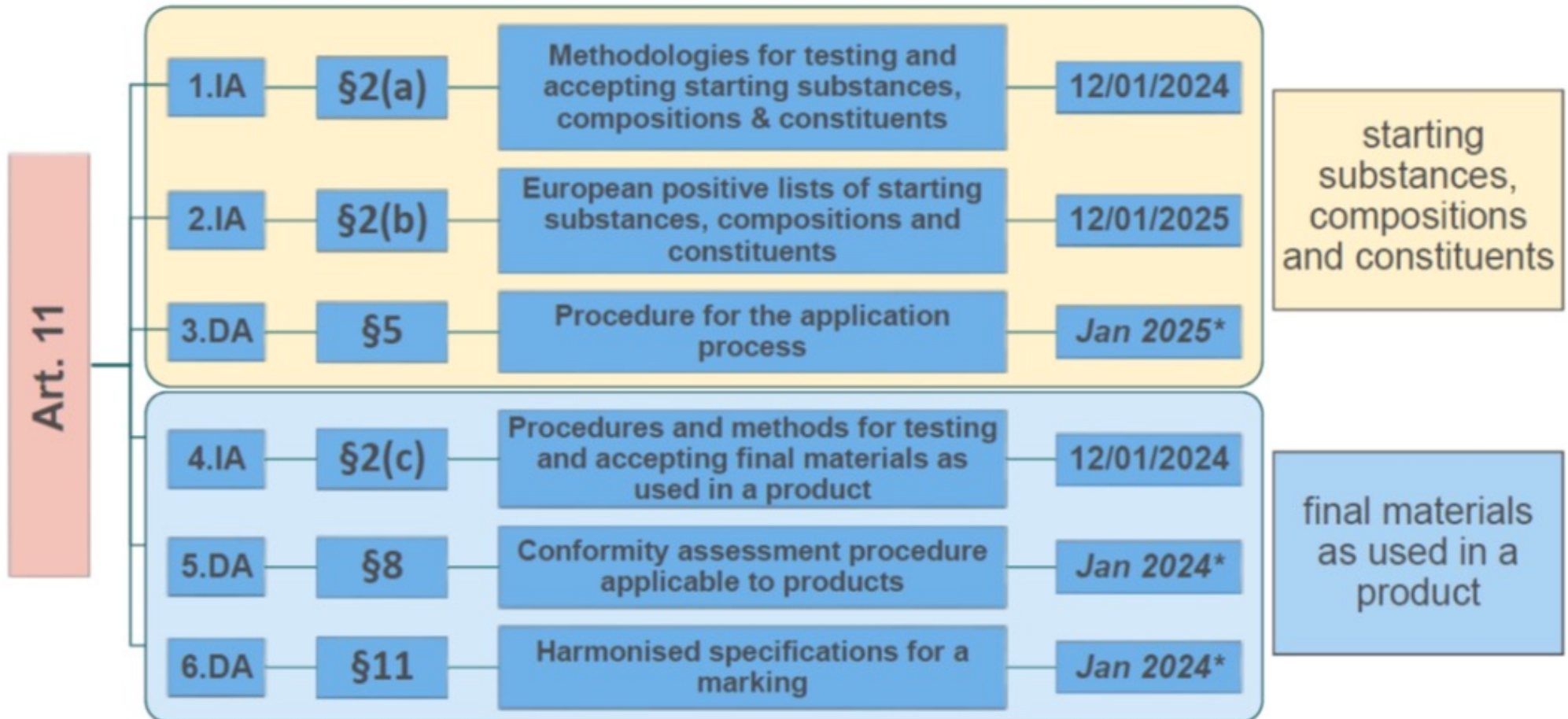
Material	Product
<p>Cement powder in bag package</p>  <p>© Par NaMaKuKQ - stock.adobe.com</p>	<p>Concrete water tank</p>  <p>© Par Phodorstock - stock.adobe.com</p>
 <p>© Par NaMaKuKQ - stock.adobe.com</p>	<p>Concrete pipes</p>  <p>© Per Czian - stock.adobe.com</p>

Material	Product
<p>Powders (kaolin, aluminum oxide, zirconium oxide)</p>  <p>© ZIU - stock.adobe.com</p>	<p>Ceramic disc in valve</p>  <p>@asadykov_stock.adobe.com</p>
<p>Enamel frits/powders</p> <p>Production of enamel:</p>  <p>@rparya - stock.adobe.com</p>	<p>Ceramic parts</p>  <p>@borapokujn - stock.adobe.com</p>
	<p>Enamelled water heaters</p>  <p>@fV5_stock.adobe.com</p>

C E M E N T I O U S

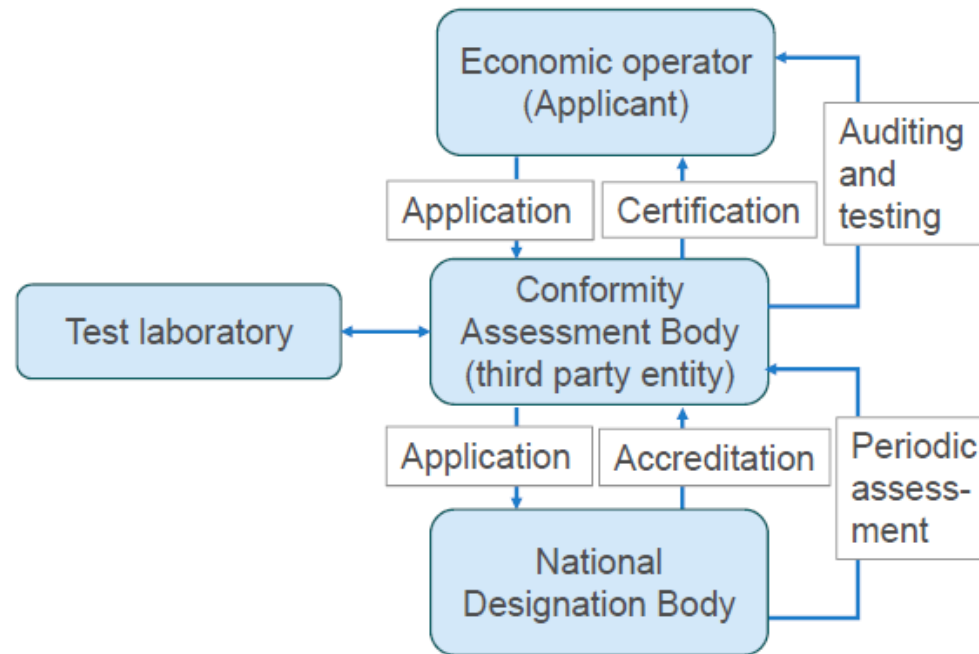
C E R A M I C S
& E N A M E L S

Implementing and delegated acts called by the DWD



(*) Commission's indicative target date, no date specified in DWD

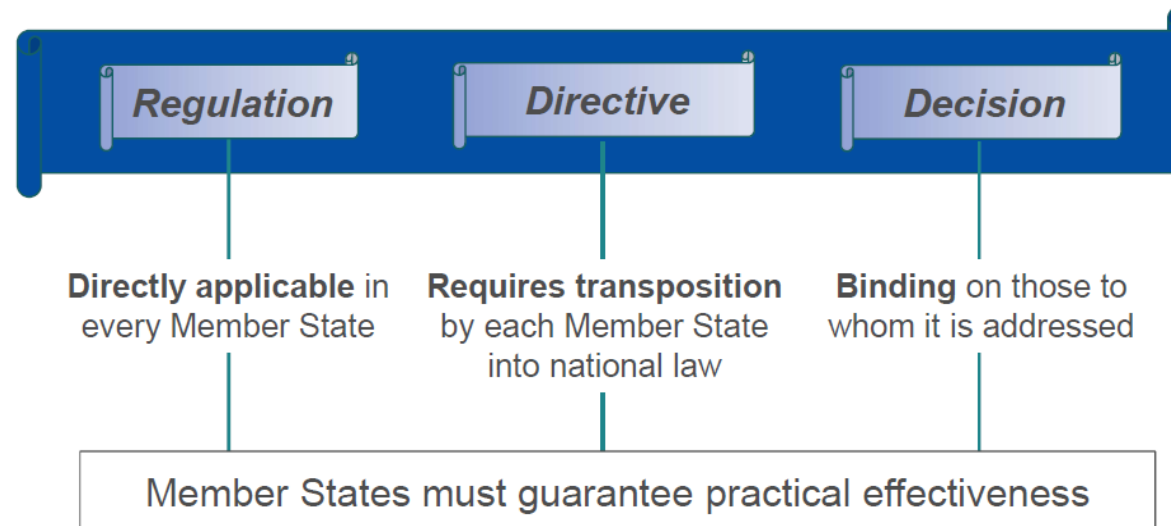
General scheme for the harmonised system



Important remarks

- Starting point = 'System 1+', a third party conformity assessment body issuing a certificate of constancy of performance
- Conformity assessment bodies: not necessarily designated in every EU Member State.

Types of implementing and delegated acts



Recommendations and Opinions are not binding

- COM empowerments in the recast DWD do not specify the type of act
- COM will decide on 'case-by-case' basis
- DG ENV envisages Decision

Recent changes in the national revision process after Dir. (EU) 2020/2184 entered into force

Art. 12 of the recast DWD states:

- For the national implementation of the requirements of this Art., Art. 4(2) (preventing deterioration of DW quality) shall apply accordingly (p. 2)
- Pursuant to p. 1 of this Art., and without prejudice to Reg. (EU) No 528/2012 (Biocide) and by using relevant EU standards for specific treatment chemicals or filter media, MSs shall ensure that the purity of treatment chemicals and filter media is assessed and the quality of such chemicals and filter media is guaranteed (p. 3)

National implementation:

A specific Annex will be included in the national transposition of the recast DWD

THANK YOU FOR YOUR KIND ATTENTION

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