Requirements for new coatings in drinking water applications

- a European view -
based on
German Requirements

Josef Klinger
DVGW-Technologiezentrum Wasser (TZW)
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TZW Water Technology Center

• Independent, non-profit organisation
• Part of DVGW with own CEO in D-Karlsruhe
• Branches in Dresden and Hamburg
TZW: Working fields

TZW Water Technology Center

Technology

Chemical Analysis

Groundwater & Soil

Microbiology

Environmental Biotechnology

Corrosion

Material Testing

H.-Sontheimer-Lab

Dresden Branch

Hamburg Branch
Drinking Water Directive

• 98/83/EC, Article 10
  Requirements for materials in contact with drinking water are up to the member states

• Link to Construction Product Directive 89/106/EEC

▶ Each member state can fix stricter requirements in the national drinking water ordinance
The German Approach

- Each substance used for the production of a material must be assessed toxicologically
- Composition check-up against positive lists (2002/72/EG, BfR, EFSA, SCF, national lists for coatings and lubricants)
- Leaching test in cold and additionally warm or hot water
- Limit values are depending on the range of use
- KTW certificate for products
Coating Guideline

- Last update: 7. October 2008
- Composition of the positive list for organic coatings
- How to include new substances in the positive list
- Requirements for organic coatings
- Test Certificate

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1.1 Starting substances for resins and curing agents e.g. Isocyanates, Polyols, Alcohols, Oxirane and Glycide Compounds ...

1.2 Fillers and pigments
Fillers: BfR Recommendation LII
Colorants: BfR Recommendation IX

1.3 Modifying agents

1.4 Solvents

1.5 Additives and accessory agents
Intermediate Products

The smallest components susceptible to migration have been included in the positive list according to their toxicological assessment

- Intermediate products with epoxy groups
- Intermediate products with amines
- Intermediate products with isocyanates
- Others
Approval process

1. Disclosure of the chemical composition against secrecy agreement at the test institute
2. Assessment of the chemical composition by the test institute (e.g. TZW)
3. After positive composition check-up testing in cold water (23°C) 3 x 72 h
   - odour & flavour, TOC-migration
   - individual substances
4. Warm or hot water testing, if ordered
5. 5 year valid test certificate for the product

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European Idea – One system

1994: CEN Seminar in Vienna
1998: Feasibility study
   (National hygienic standards not lowered)
1999: RG-CPDW
2001: Mandate 136 to CEN under CPD, DWD
2002: Commission Decision on procedure 1+
2003: EU Research Programme
2005: EAS on paper

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EAS: The European Frustration

2005: RG CPDW → EG CPDW

2006: Revised mandate
EG – CPDW was withdrawn

2007: 4 MS Group
way out of the blockage

2008: Feasibility study by 4 MS

2009: Official letter about „no – EAS“ to CEN

2010: Revision of the mandate?
EAS will be withdrawn?

TZW
The European Chance

• 4 Member States (MS)
  (Germany, France, Netherlands, UK)

• Find a common proposal
• Defining the common approach
• Implementation in national schemes
• Mutual recognition could be possible
# The European Chance

<table>
<thead>
<tr>
<th>STEP</th>
<th>France</th>
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<th></th>
<th>Germany</th>
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<th>The Netherlands</th>
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<th></th>
<th>United Kingdom</th>
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</thead>
<tbody>
<tr>
<td>1. Application: full formulation, production process details</td>
<td>X</td>
<td>-</td>
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<td>X</td>
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<td>X</td>
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<tr>
<td>2. Check on details of application</td>
<td>-</td>
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<td>X</td>
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<td>X</td>
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<tr>
<td>3.1 - F, D, NL: Check on compliance with regulations (e.g., PL, CL, ACL)</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>-</td>
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<td>Test lab</td>
<td>-</td>
<td>X</td>
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<td>3.2 - Assessment protocol in case of non-compliance with regulations (e.g., PL, CL, ACL)</td>
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<td>X</td>
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<td>4. Pre-certificate auditing of factory, producers control system and sampling of initial type testing</td>
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<td>5. Laying down of test protocol</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>-</td>
<td>X - UBA guidelines</td>
<td>Product standards (DVGW – standards incl. UBA guidelines, DIN standards)</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>General tests plus specific ingredients on basis of toxicological review</td>
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<td>6. Initial type testing</td>
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<td>Test lab</td>
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<td>Process</td>
<td>France</td>
<td>Germany</td>
<td>The Netherlands</td>
<td>UK</td>
<td>Common proposal</td>
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<td>Pre-test sample treatment</td>
<td>1 h in flowing tap water, 24 h in chlorine free test water + 3 test water rinses (1 sample with disinfection treatment - 24 h in 50 mg Cl/l)</td>
<td>As in EN 12873-1 &amp; 2, except no pre-test disinfection treatment</td>
<td>As in EN 12873-1 &amp; 2, except no pre-test disinfection treatment used</td>
<td>As in EN 12873 series of standards, except no pre-test disinfection treatment used</td>
<td>As in EN 12873-1 &amp; 2 – Amend standards to remove pre-test disinfection option.</td>
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<td>Test Water</td>
<td>1. Chlorine free demineralised water</td>
<td>Chlorine-free ultrapure water</td>
<td>Chlorine-free ultrapure water</td>
<td>1. Chlorine free ultrapure 2. Chlorinated (1 mg/l) ultrapure water</td>
<td>Chlorinated and/or chlorine-free dependent upon individual Member State – additional testing may be required if only chlorine-free test water used</td>
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<td>Number of test samples tested</td>
<td>Single testing for each water type plus blank test</td>
<td>Duplicate + blank test</td>
<td>Duplicate</td>
<td>Duplicate – one for each water type – see comment below</td>
<td>Duplicate testing for each water type except for GC-MS</td>
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<td>SV/ test ratio</td>
<td>0.03 to 2.4 dm$^{-1}$ depending on final intended use</td>
<td>As in EN 12873-1 &amp; 2 Pipes filling: min 5 dm$^{-1}$</td>
<td>Pipes: 5 – 40 dm$^{-1}$</td>
<td>As in the BS EN 12873 standards</td>
<td>As in EN 12873-1 &amp; 2 - jg.30</td>
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<td>Leaching sequence</td>
<td>1 x 24 hours (20$^\circ$C)</td>
<td>As in EN 12873-1 &amp; 2 3 x 72 hours (23$^\circ$C) plus, if required</td>
<td>3 x 72 hours (23$^\circ$C) or (3)</td>
<td>As in EN 12873 – i.e. three sequential 72 hour contact periods – cold water only. The UK does not currently do hot water migration studies on products.</td>
<td>As in EN 12873-1 &amp; 2 - Further leachates (maximum 7 extra) tested, if required, for die-away studies. See General Background Note 1 under Table 4 concerning hot water testing.</td>
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<tr>
<td>Leachates analysed</td>
<td>1$^{st}$ for all determinands</td>
<td>As in EN 12873-1 &amp; 2 All 3 leachates (23$^\circ$C)</td>
<td>All 3 leachates.</td>
<td>All 3 leachates</td>
<td>As in EN 12873-1 &amp; 2 – Further leachates (maximum 7 extra) tested, if required, for die-away studies. See General Background Note 1 under Table 4 concerning hot water testing.</td>
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The Actual Situation

- Hygienic requirements are still regulated by the member states
- Positive lists have to be harmonised under 4MS
- Testing has to be harmonised under 4 MS
- Other MS may join

→ ..... a long way ......
Summary

• Germany has a well defined system
• New materials are bound to positive lists
• „Bureaucracy has killed the EAS”
• Voluntary 4 MS approach could be a way out
• National requirements are staying in force