Lessons learned and the need for European harmonisation

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Products: Source to Tap
Safe drinking water for the European citizens is the overall essential!

Materials and products in contact with drinking water could impair the drinking water quality by:
- Leaching of substances at levels that are avoidable or could pose a risk to human health
- Enhancement of microbial growth that could pose a risk to human health
- Odour and flavour problems

Safe materials are part of a holistic Water Safety Plan (WSP) concept

Materials/products often (semi-) permanent in drinking water system - consumer dependency, life time exposure; not easy to replace and costly

To guarantee fitness for use approval, certification and clear marking is necessary

Market oriented legislation, i.e. EU wide harmonization of hygienic requirements, is necessary but missing:
1) Protection of health of European citizens
2) Pursuit for an economic level playing field/removal of trade barriers
3) Saving costs for all players (users, producers and governments)
Examples of historical incidents

- **Lead** (all MS) – pipes, plumbing (not allowed to be used any more)

- **PVC pipes** (type used around 1970/1980 – VCM (f.e. FR))

- **Polycyclic aromatic hydrocarbons (PAH)** in bitumen based materials (MS) – odour, flavor and health risks

Replacement of lead

<table>
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<th>Total Cost (Mrd. €)</th>
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- Estimated cost of pipe exchange per household: ~ 1500 €

- Transition period 15 Years, but start in EU 1998 (~2013)!

Source: WRC, 1995
Examples of historical incidents

Coliforms on EPDM in a gate valve, Dr. Bendinger, Hamburg (D)
Examples of historical incidents

Macro-colonies on seams in a drinking water reservoir (Schoenen 2011)
Examples of historical incidents

Legionella on a membrane in an expansion vessel (Schoenen 2011)
Examples of new incidents

- **Metallic materials** – e.g. leaching lead and nickel from sanitary taps, unsuitable alloys (NL, DE)

- **Bisphenol A** – epoxy lining (Sweden, Germany) (NB might be due to processing by application)

- **Microbial growth** – plastics/rubbers – showerheads (risk growth of pathogens under which Legionella) (various MS)

- **Odour** – not reported change in production process PEX tubes (Czech Republic)
A SUMMARY on Article 10 DWD dilemma

- **Art 10** asks for national regulations – obligation in general terms, not an operational framework, will not automatically lead to harmonisation of requirements

- Causes **conflicts**: mutual recognition is based on assumption, that all MS fulfill directive tasks - uniform consumer protection level, free market

- DWD asks for **minimisation** of migration of substances and DBP, DWD gives examples to regulate substances originating from materials by product specification, WHO supports this in practice only feasible approach

- COM announced **EAS system** for years, MS without appropriate system waited for EAS to come, COM withdrew attempts for EAS and therewith an efficient basis for **mutual recognition** of products

- **EU institutions** (Europ. Court etc.) urge MS to define conditions for **mutual recognition** > 4 MS initiative is “fill-in“ for missing harmonisation of requirements
No EAS?
- Despite broad support for proposal (Regulators, Industry, DW) – transparency, protection human health, removal barriers to trade
- Questioned by EC (legal framework within CPR, required resources for operational management)

Next best
- EU wide convergence of national schemes providing a basis for mutual recognition and harmonisation, *inter alia* under the Construction Products Regulation (CPR)
- Conditions
  - Set of supporting standards (ENs by CEN) complying with regulatory (health related) requirements
  - One (high) level of attestation of conformity (Commission Decision 2002/359/EC; third party approach))
  - Harmonisation (Common framework) of health related requirements (amendment of DWD could be instrumental)
4/5 MS common approach – initiative towards harmonisation

candidate:
National Acceptance Schemes – legal framework

- **National regulations**

Based on:
- Drinking Water Directive (98/83/EC)
- Construction Products Regulation (EU) 305/2011
- Biocides Regulation (EU) 528/2012 – disinfectants
- Other product directives
- Supporting test standards (ENs) developed by CEN on basis of mandates given by European Commission (Mandate 136)

And: principal of mutual recognition
- Non-harmonised products (Regulation EC 764/2008)
- Exemptions:
  - Overriding reasons of public interest
  - European Treaty (Article 30)
Overview NL

- Historical grown (early 1930) from an accepted voluntary system to a mandatory system in 2003.

**Early years**
- 1948: Foundation of Kiwa by drinkingwater suppliers
  - Kiwa BRL: technical aspects/certification

**Toxicological aspects**
- 1976: Commission Health Aspects materials and chemicals in contact with drinking water – inter alia WHO advice
- 1980: 1st Inspection Guidance
  - Introduction positive list for organic materials
  - After DWD 1998: Extension of the assessment scheme in NL
  - Kiwa – ATA (ATA = attest toxicological aspects); nowadays HA = Hygienic Aspects (Microbiological, organoleptic & toxicological aspects)

- 2003 and 2011 Notified Ministerial Regulation
Overview NL

- **Scope:** all products from source to tap

- **Drinking Water Act (2011)**
  - Minister sets health related requirements for materials and chemicals

- **Drinking Water Decree (2011)**
  - Water supplier shall ensure that materials and chemicals used in water supply do not impair drinking water quality
  - Tool: approved quality declaration of conformity with requirements
  - Commission of Experts: performance of approval conform Regulation

- **Construction Decree (2012):** in house installations

- **Materials and chemicals in the supply of drinking water and warm tap water Regulation (2011)**
  - Test requirements, pass/fail criteria, certification, procedures
  - Based on outcome of research programme, EAS Proposal, 4/5MS results, supporting test standards (EN)
  - Mutual recognition: equivalent of a recognised quality statement, *provided the Minister deems the quality certificate of the other state in compliance with similar or better criteria than those set forth in the present Regulation*
NAS NL – facts and figures

Number of Products certified in NL
• 550 contracts (CI Kiwa)

Costs (depends strongly upon complexity product)
• Approval procedure € 2000 - € 40.000 (Median € 6.000)
• Certification contract € 1000 - € 15.000 / yr (Median € 2.100)

Mutual recognition
• Compliance check by Commission of Experts: no procedure put through by applicants yet
NAS NL– non conformities

Positive effect mandatory regulation and post-certification audit

![Bar chart showing NAS NL non-conformities post-certification audits from 2000 to 2013. The x-axis represents years from 2000 to 2013, and the y-axis represents percentage. The chart shows a trend of decreasing non-conformities over the years.]
Historically grown (since 40 years) functioning system based on an **overall accepted voluntary system of certification** relying on

- UBA-guidelines and technical rules and
- the demand for certified products by users

Government tries at the moment to save the consumer protection level by transforming former guidelines on hygienic requirements to **mandatory acceptance criteria documents**. > legal security

Basis of transparent conditions for defining requirements for **recognition** of other MS’s systems > equivalent consumer safety level
Requirements

Federal Ministry of Health

Federal Environment Agency (UBA)

Federal States

DW Ordinance

Guidelines / Evaluation criteria
Acceptance System

Accredited Certifier

Test Houses within accredited system

UBA Guidelines / § 17 DWO Evaluation criteria

Standards (e.g. CEN, DIN, DVGW)
Lessons learned – how to choose the right product?

No market oriented legislation

**Users** (drinking water suppliers, installation branch, consumers):

- Lack of transparency reg. fitness for use (marking/labeling)
- Lack of availability of products fit for use in contact with drinking water

→ Health risks, replacement costs
Lessons learned – national requirements versus European and international market

COM shifts dilemma to MS and European Court,

risking to lower consumer protection in affected EU-MS

Not creating an equal level playing field
Examples of savings on certification/testing

Based on quick model calculations

- Bureau Leiding (Dutch plastic piping industry):
  330,000 Euro/5jr per manufacturer harmonisation 4MS (2012)
  X (multiplying to 28 MS)

- Grohe (sanitary fitting industry):
  450,000 Euro/5jr harmonisation 3MS of 1 requirement/3 products (2009)
  X (multiplying to 28 MS)
Lessons learned - Governments MS – Feasibility national systems

- **28 systems** – administrative burden, costs and capacity

- Not feasible to assess all products on MS level vs European market – resources are limited

- Mutual recognition difficult to execute without coordination and interpretation (precautionary principle, minimisation request)

- If product causes problems after fixed installation withdrawal practically impossible

- Enforcement/Surveillance - Difference between placing on the market (CPR) and requirements for use (legislation on MS level)

→ System inefficient and impossible to comply with all provisions (free market, high consumer protection level), multiplying costs and capacity, surveillance difficult
Lessons learned – voluntary harmonisation

• 4/5 MS: Incremental approach

• Implementation of VOLUNTARY common approaches depends on national procedures and policy

• Limited by human and financial resources

It is not possible to
- firstly get a perfect system started and
- secondly not at the same time
4/5-MS-Initiative:
Process of mutual recognition of National Acceptance Schemes of 5 MS for products in contact with drinking water concerning their hygienic safety
Mutual recognition of National Acceptance Schemes of all MS for products in contact with drinking water concerning their hygienic safety = EU Harmonised System
Lessons learned – CPR/harmonised product standards

• **CPR (market oriented legislation) will not lead to overall harmonisation:**
  CEN M136: Product standards hEN (still to be developed): testing methods (EN) and the criteria
  **Criteria** – compilation of all notified regulated national requirements for the product in question in the EU – differences between MS will remain

Currently Mandate 136 is withdrawn.

• How will it be replaced?
• Open questions remain!
• Who is responsible/takes responsibility for harmonisation of the hygienic criteria?
Opportunity = now

- **Aims of 7th EAP** to safeguard the Union’s citizens from risks to health and well-being

- **ECI Right2Water**: access to safe drinking water

- **Outcome of EC Public consultation** on the quality of drinking water in the EU

- **Better regulation - Refit programme – review of DWD in 2015**

Ex ante evaluation/Impact Assessment
DG GROW, DG SANTE, DG ENVI

(16) The Union has agreed to achieve, by 2020, the objective that chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment 

(d) the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed in all relevant Union legislation, and risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimised. Long-term actions with a view to reaching the objective of a non-toxic environment will be identified;
EC PLAYING "OLD MAID"

I HAVE TO GET RID OF THIS CARD BEFORE THE GAME ENDS...

MATERIALS IN CONTACT WITH DRINKING WATER
CONCLUSIONS

• Voluntary mutual recognition depends on implementation of harmonised acceptance schemes in MS

• Incremental approach and adequate management is needed

• EU harmonisation/EU regulation on materials in contact with drinking water is needed (uniform level of protection, equal level playing field, saving costs for all parties involved)

• COM is invited to take initiative