



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Coatings in the Council of Europe

Update of the Technical Guide

Bianca van de Ven



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

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Council of Europe (CoE)

Memorandum of Understanding between EU & CoE (2007) to intensify cooperation, with the aim of:

- implementing common strategies and programmes
- ensuring legal coherence
- searching for added value
- making better use of existing resources
- avoiding duplication
- fostering synergy

Same advantages will apply for cooperation of MS's with other MS and EU organisations :

CoE (EDQM), EC (WGE-FCM), EFSA (FIP-network), JRC...



EDQM / P-SC-EMB

EDQM = European Directorate for the Quality of Medicines & HealthCare

P-SC-EMB = Committee of Experts on food contact materials, and its working groups

- open to 37 countries + EU incl. EFSA, JRC, + observers
- Plenary sessions: 2 times a year, in Strassbourg
- Meeting working groups: flexible in time and place; \pm 1-2 times a year

Website:

<http://www.edqm.eu/en/consumer-health-protection-1415.html>



Policy statement on Coatings 2004(1)

Policy statement on coatings comprises of 2 documents:

- ResAP (2004) 1: Framework Resolution on coatings intended to come into contact with foodstuffs
- Technical Document No. 1 – List of substances to be used in the manufacture of coatings (version 3; 12.02.2009)



RESAP (2004) 1 on coatings

Scope

Coating is the finished material, mainly organic, applied to a substrate to form a film/layer, mainly to protect and/or to impart a technical function.

- Coatings for metal packaging
- Flexible packaging coatings
- Heavy-duty coatings



Res AP 2004(1) on coatings

Specifications

- Absence of transfer of constituents in quantities that endanger human health or deteriorate the product (= Art.3 1935/2004)
- According to GMP (=2023/2006)
- Restrict substance use to:
 - Substances in positive list for coatings (see Tech. Doc. 1)
 - Aids to Polymerisation (AP's) for plastics in ResAP(92)2
 - Substances in national regulations for coatings
- Be compliant with:
 - Restrictions and specification in the positive lists
 - OML = 10 mg/dm², or 60 mg/kg food (containers of 0.5- 10 L)



Technical Document on coatings

Lists of substances for use in coatings (and its restrictions):

- List A: monomers and other starting substances assessed by SCF
- List B: monomers approved by MS's (of former Partial Agreement) or by the FDA, applying the criteria at the time of their approval
- List C: additives assessed by SCF
- List D: additives approved by MS's (of former Partial Agreement) or by the FDA, applying the criteria at the time of their approval

Monomers (list A+B) and additives (list C+D) have been evaluated by:

- SCF/EFSA (classified SCF-L 0-4A, see 'Synoptic Document')
- Member states
- FDA

Restrictions: - primary aromatic amines (<0.01 mg/kg)
- list of other specifications, mainly purity requirements



NEW Framework Resolution (under preparation)

Scope: All FCM's not covered by specific legal provisions in EU.

- Only substances that have been evaluated by RA can be used in the manufacture of FCM
- Indicated by the TG's, the lists of evaluated substances can either be:
 - 'Positive lists' (PL), excluding the use of non-listed substances; **OR:**
 - non-listed substances > self assessment (DoC & supporting info)
- OML = 10 mg/dm², or 60 mg/kg food
- Restrictions (SML/SRL, QM, QMA,...) have to be met
- Proper labelling of utensils (to avoid use conditions that are not safe)
- Traceability of materials
- Verification by migration testing
- Declaration of Compliance and supporting documentation



Framework Resolution (cont.)

General structure of the Technical Guides should be:

- 1) General provisions (especially purpose/scope, additional definitions);
- 2) (Specific) requirements related to the particular material
- 3) List of evaluated substances used for the particular type of FCM, including: relevant restrictions and specifications applicable to them,
OR: (if justified) a list of non-evaluated substances known to be used;
- 4) testing conditions and methods of analysis;
- 5) additional information relating to the declaration of compliance, if applicable.



Ad Hoc Working Group on coatings

Goal: Revise the Framework Resolution on coatings and the associated Technical document no.1 (Lists of substances)

Not yet started, but:

- Exploratory meeting held between BE and NL
- Presentations given in Plenary meeting on BE and NL coatings legislation
- Expression of interest also from DE

'Wait' for:

- Framework Resolution on FCM is adopted
- (substantial) revision of NL on coatings is adopted



Plans for the update

- Update for new format into Technical Guide
- Update of the lists of substances and their limits
- Specify testing conditions and methods of analysis, as far as they deviate from testing conditions in framework Resolution
 - Alternative simulants?
 - How to deal with nano particles?
 - Limits on coatings for common NIAS's?
 - Suggestions anyone?

Thanks for your attention!