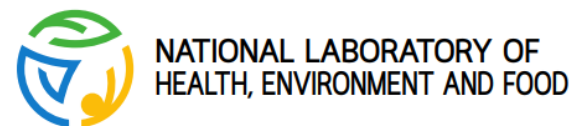


THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



Council of Europe activity on enamels

Viviana Golja and Andreja Zorič
on behalf of the ad hoc group on enamels



Outline

- About food contact enamels
- Why is it important to deal with them
- About the Technical Guide

Food contact enamels

Thin layer of vitreous (glassy) inorganic silica coating bonded to metallic substrate by fusion at temperatures above 480°C and used for:

- protection of the substrate underneath from corrosion and physical damage
- modification of structural characteristics of the substrate
- decoration

Metallic substrates:

cast iron, stainless steel, aluminium, copper

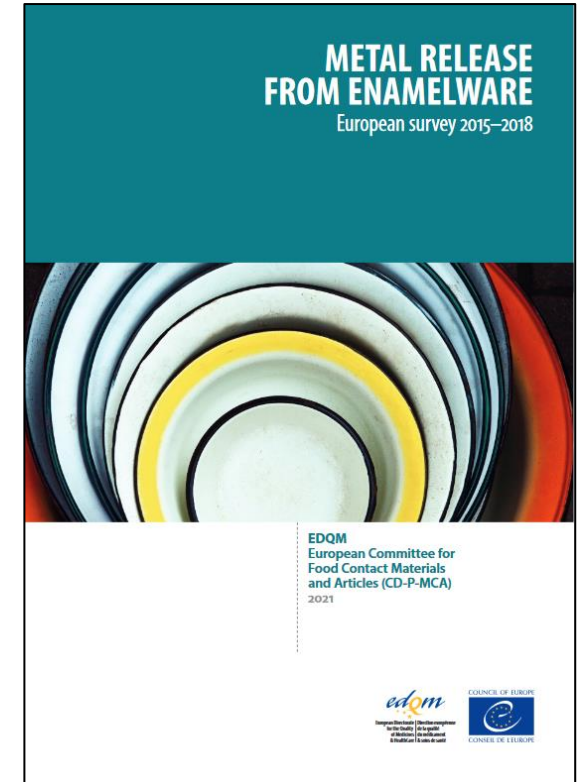


Food contact enamels

- Enamels vs ceramics:
 - **Metallic substrates**
 - Substances for glaze are similar to ceramics
 - Enamel manufacturing - in some cases **lower** temperatures than manufacturing of ceramics due to melting of enamel substrate
 - Enamels main use: **cookware and baking trays**

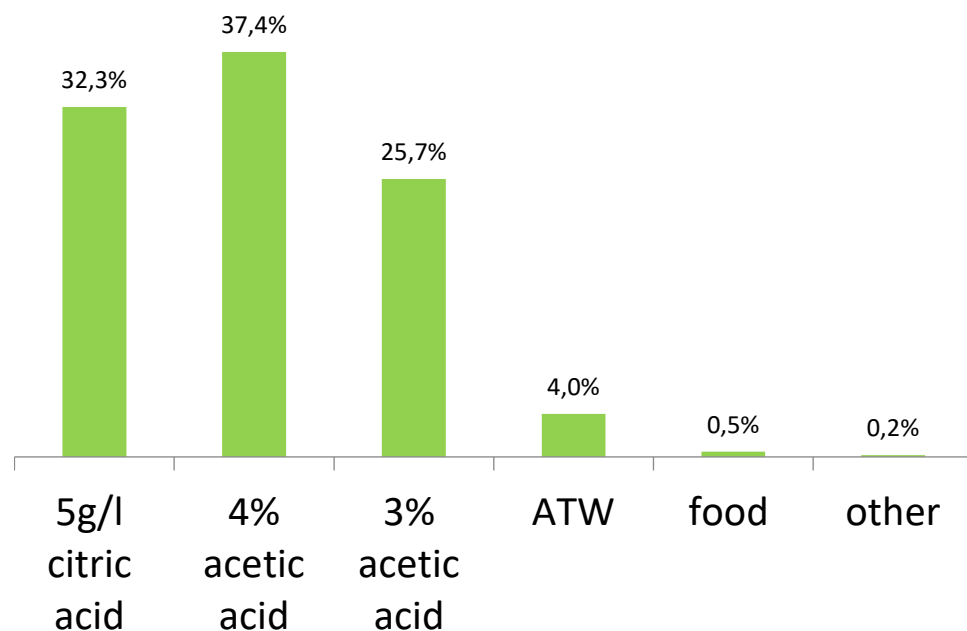
European survey

- Questionnaire for CoE MS:
 - no. of tested samples in 2015-2018
 - test methods and test conditions applied:
 - ❖ simulant, time/temperature conditions, surface/volume ratio
 - limit values used for compliance assessment
 - number of samples exceeding limits, type of article, colour of enamel layer, country of production
- 7 countries sent results
- Survey is available on <https://freepub.edqm.eu/publications/>

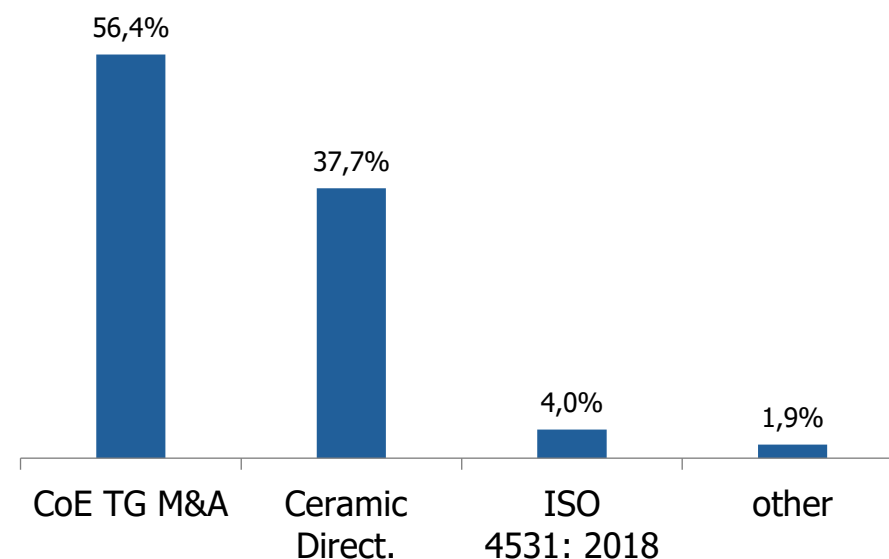


Release testing of enameled articles - European survey

Simulants



Time/temperature conditions



Limit values used:

- CoE Technical Guide on metals; CoE transitional values; EEA guidelines; ISO 4531; other (national measures)

European survey conclusions

- Variability of test conditions and limit values used for compliance assessment
- Limits exceeded in most reported cases - Co, Li, Al, As, Cd and Ni
- Need for harmonisation of test conditions and limit values!



Ad hoc group on enamels CoE
(BE, DE, ES, FR, GR, HU, SI, TR, JRC)



Tasks:

- compiling scientific/professional information on the release of elements from enamel into foods and simulants
- identifying substances that are frequently used in the manufacture of enamels
- **Drafting a Technical guide on food contact enamels:**
 - specific release limits (SRLs)
 - analytical method: simulants and test conditions



Technical Guide (similar structure to metals & alloys TG)

...

- Introduction: definition of enamels, functionality of substances used in the production of FC enamels
- Safety review and recommendations of enamel components including SRLs
- Release testing of food contact materials and articles made from enamels: simulants and test conditions



Testing method:

- Test customised enameled plates releasing significant amounts of elements
- New simulants and test conditions to be compared with real food use (avoid excessive overestimation of release). For now:
 - acetic acid (3% and 4vol%), 5g/L citric acid, acidified ATW (artificial tap water at pH 3.5)
 - artificial apple juice, ...

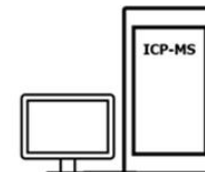
choice of food simulant, time, temperature



release testing



measurement of element concentration





Use of ISO 4531 release test lab apparatus, migration test cells, article filling method

Elements of interest: constituents of enamel coatings

Recent meeting in the beginning of September 2024

Ad hoc group

Katharina Adler, DE, Celia Azoyan, FR, Jose Blanca, ES, Juana Bustos, ES, Semra Cavus, TR, Karlien Cheyns, BE, Heidi Demaegdt, BE, Ingo Ebner, DE, Viviana Golja, SI, Helma Haffke, DE, Eddo Hoekstra, JRC, James Snell, JRC, Blanca Szilvassy, HU, Benjamin Teneul, FR, Despina Triantou, GR, Hatice Uslu Yilmaz, TR, Andreja Zorič, SI

EDQM Secretariat: Susanne Bahrke and Teresa Carrilho

Thank you for your attention



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