

## 附錄

附錄一、食品接觸物質及器具委員會(CD-P-MCA) 第三次全體會議議程

附錄二、簡報-礦物油在荷蘭的毒物學數據及攝食暴露探討

附錄三、琺瑯(enamels)金屬釋出調查報告

附錄四、State of work



**SECRETARIAT**

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**European Directorate for the Quality of Medicines and HealthCare (EDQM)**

**Committee for Food Contact Materials and Articles (CD-P-MCA)**

**CONVOCAATION**

**3rd plenary session of the Committee for Food Contact Materials and Articles  
(Partial Agreement) (CD-P-MCA)**

**28 May 2019, 09:00-18:00**

**29 May 2019, 09:00-17:00**

**EDQM, 7 allée Kastner, CS 30026, 67000 Strasbourg, France,**

**Room 200**

**FINAL AGENDA**

**1. OPENING OF THE MEETING**

**2. DECLARATION OF INTEREST/CONFIDENTIALITY**

Any (financial) interests related to an item on the agenda of the present meeting need to be declared at the opening of the meeting.

*Reminder:* Each participant has to provide the EDQM with a formal declaration of their interests and respect for confidentiality [FORM/226]. The EDQM must be notified in case of any change to the information provided.

**3. ADOPTION OF THE AGENDA**

***Reference document:***

**PA/PH/MCA (18) 24 FINAL** Final meeting report of the 2nd plenary session of the CD-P-MCA, held on 5-6 November 2018 / 2nde session plénière, rapport final, CD-P-MCA, 5-6 novembre 2018

**4. CD-P-MCA WORK PROGRAMME**

**Working document:**

PA/PH/MCA (18) 12 R2 State of work

**Reference document:**

PA/PH/MCA (18) 1 Terms of Reference of the CD-P-MCA 2018-2019 / Mandat du CD-P-MCA 2018-2019

**5. RENEWAL OF THE CHAIR**

The term of office of the Chair shall be one year. It may be renewed once.

Source: Resolution CM/Res(2011) 24 on intergovernmental committees and subordinate bodies their terms of reference and working methods

**6. GENERAL ITEMS AND EXTERNAL RELATIONS**

All delegations to report from relevant meetings or activities.

**Related Topics:**

National regulations / guidelines

EU FCM legislation evaluation

JRC Kitchenware guideline/tool

EFSA FCM Network

**7. STANDARD SETTING ACTIVITIES – WORK IN PROGRESS**

**7.1 Common criteria for materials and articles – towards an FCM resolution**

*Rapporteur: K. Adler (Germany)*

Progress report

Discussion on Chapter 3 of the Draft Resolution.

**Reference document:**

PA/PH/MCA (18) 9 R1 DRT Draft Resolution CM/Res(201X) Y... on the safety and quality of materials and articles intended for contact with food and with pharmaceuticals – including comments made by 7 October 2018.

**7.2 Compliance Work**

*Rapporteur: R. Meuwly (Switzerland)*

**Working document:**

PA/PH/MCA (18) 25 R2 Draft technical guide on compliance documentation for food contact materials – revised document April 2019.

Comment here

**Reference documents:**

PA/PH/MCA (18) 25 R1 DRT Draft technical guide on compliance documentation for food contact materials – revised document including comments made by 31 March 2019.

PA/PH/MCA (18) 25 R1 Draft technical guide on compliance documentation for food contact materials. Submitted by Dr R Meuwly and Dr K Grob (Switzerland).

**7.3 Paper and Board**

Progress report

***Working document:***

PA/PH/MCA (19) 8

Draft technical guide on paper and board materials and articles – revised document April 2019.

Comment here

Deadline for comments 18 May 2019.

***Reference documents:***

PA/PH/MCA (19) 9

12th meeting draft report, ad hoc working group on paper and board, 27 March 2019.

PA/PH/MCA (18) 23 FINAL

11th meeting final report, ad hoc working group on paper and board, 2 October 2018.

PA/PH/MCA (18) 13 DRT RI

Draft technical guide on paper and board materials and articles – including amendments and comments by 28 September 2018.

PFAS in food contact materials, a presentation by Dr Bianca van de Ven, RIVM, National Institute for Public Health and the Environment, Netherlands.

Mineral oils – Review of toxicological data and dietary exposure in the Netherlands, a presentation by Dr Bianca van de Ven, RIVM, Netherlands.

Mineral oils in food; a review of toxicological data and an assessment of the dietary exposure in the Netherlands, RIVM Letter report 2017-0182, B.M. van de Ven et al.

Report of ESCO WG on non-plastic Food Contact Materials, published 25 July 2011 by the European Food Safety Authority: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2011.EN-139>

Annex I. Compilation of lists of substances for non-plastic Food Contact Materials, evaluated in Member States, Switzerland and Norway, as collected by the ESCO Working Group

#### 7.4 Coatings

*Rapporteurs: E. Heyvaert (Belgium), B. Van de Ven (Netherlands)*

Progress report

Enquiry on behalf of Coatings Task Force  
Workshop on Varnishes and Coatings

#### 7.5 Metals and Alloys

*Rapporteurs: E. Heyvaert (Belgium), I. Ebner (Germany)*

Progress report

***Working documents:***

Summary of Teleconferences for the sections on Al, Cr, Mg, Ni, Ag, Tl. Edit here .

PA/PH/MCA (19) 10

Metals and Alloys Technical Guide – chapter 2 compilation Al, Cr, Mg, Ni, Ag, Tl in track change version – revisions for the second edition. Deadline for comments: 31 July 2019.

Documents for Comment

Current draft

Metals and Alloys Technical Guide – chapter 3 – draft May 2019

PA/PH/MCA (19) 4

Metals and Alloys Technical Guide – draft section on zirconium, submitted by Bianca van de Ven, RIVM (Netherlands).

**reference documents:**

M&A - Technical Guide 1st ed Document uploaded for comments and proposals for amendments

PA/PH/MCA (18) 19 DRT Metals and Alloys Technical Guide – chapter 3 with revisions for the second edition – including comments received by 15 October 2018.

PA/PH/MCA (19) 7 Communication from Stakeholders: Letter from Patrick Llobregat, President of FEC, regarding the ad hoc working group on metals and alloys, 27 November 2018.

EFSA-Q-2019-00214 Request for an update of the EFSA scientific opinion on the risks to public health related to the presence of nickel in food and drinking water. Can be found [here](#) with the mandate number M-2019-0074.

Topics for consideration in the future. Edit [here](#).

## 7.6 Enamels

*Rapporteur: V. Golja, A. Zoric (Slovenia)*

**Working document:**

Release of metals from enamels Presentation by Dr V. Golja

**Reference document:**

Data Collection Template Enamelware collection of data on release of metals

## 7.7 Printing Inks

*Rapporteur: E. Lampi (Greece)*

Progress report Presentation by Dr E. Lampi

**Working document:**

PA/PH/MCA (19) 11 Draft Terms of Reference 2019-2020 for the ad hoc working group on printing inks

**Reference documents:**

PA/PH/MCA (19) 2 FINAL 4th meeting final report, ad hoc working group on printing inks, 19 February 2019

PA/PH/EMB (16) 8 FINAL Terms of Reference for an ad hoc working group on printing inks

## 7.8 Resins for ion exchange and adsorption

*Rapporteur: E. Heyvaert (Belgium)*

Progress report

**Reference documents:**

PA/PH/EMB (12) 7 R4 Draft Technical Guide on Synthetic ion exchange and adsorbent resins

PA/PH/EMB (12) 9 Council of Europe Policy Statement concerning Ion Exchange and Adsorbent Resins in the processing of foodstuffs – Version 3, 28.01.2009

## 8. STANDARD SETTING ACTIVITIES – WORK NOT STARTED OR SUSPENDED

For discussion if items should be pursued.

- Colourants: Germany (suspended)
- Lead leaching from glass: Germany. Suspended, pending amendments on ceramics and glass in the EU.
- Polymerisation aids: Germany
- Rubber products: the Netherlands

## Cork stoppers

Rapporteurs: pending

## 9. ANY OTHER BUSINESS

- German-Swiss collaboration on printing inks
- Improving transparency of national risk assessment – proposals by Germany

## 10. DATES OF NEXT MEETINGS

4th plenary meeting of the CD-P-MCA: 4-5 December 2019 (2d, Strasbourg, tbc).

## CD-P-MCA GENERAL DOCUMENTATION

### COUNCIL OF EUROPE / EDQM

#### 1) *Mission and objectives of the EDQM*

<https://www.edqm.eu/en/EDQM-mission-values-604.html>

*Please consult the EDQM website for detailed information on*

- *Committee for food contact materials and articles – CD-P-MCA, Steering Committee*

#### 2) *Objectives and working methods*

Terms of reference (ToR)

PA/PH/MCA (18) 1

Terms of Reference of the CD-P-MCA Committee for Food Contact Materials and Articles

#### 3) *List of CD-P-MCA appointed national representatives: Available on the EDQM Extranet dated May 2019*

Declaration of Interests and Confidentiality undertaking of the European Directorate for the Quality of Medicines and HealthCare (EDQM) Group of Experts, Working parties, Committees and staff - Form 226

#### 4) *Council of Europe Policy statements* prepared under the PA Social and Public Health (before 2009) on Coatings, Cork, Printing Inks, Ion exchange resins, Paper and board, Silicones etc.

#### 5) *Council of Europe's Committee of Ministers*, presided by a rotating chairmanship held for a six-month term in turn by the representatives of the members in English alphabetical order.

## EU – Basic legislation

### - *Food Contact Materials*

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (text with EEA relevance).

Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (text with EEA relevance).

Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food

Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Commission Regulation (EC) No 1831/2003 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (text with EEA relevance).

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, ... repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council.

- *Human medicines*

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [See amending acts].

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (text with EEA relevance).

Volume 4 of "The rules governing medicinal products in the European Union", guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

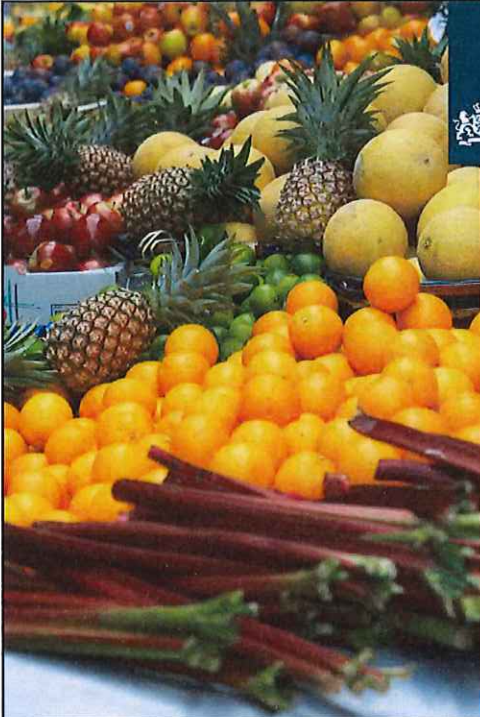
Guideline on plastic immediate packaging materials, CPMP/QWP/4359/03 EMEA/CVMP/205/04, Committee for medicinal products for human use (CHMP) and Committee for medicinal products for veterinary use (CVMP), European Medicines Agency.


- *Veterinary medicines*

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. EU rules on the authorisation, import and production of veterinary medicines [See amending acts].

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (91/412/EEC).








Rijksinstituut voor Volksgezondheid  
 en Milieu  
 Ministerie van Volksgezondheid,  
 Welzijn en Sport

**Mineral oils –**  
 Review of toxicological data  
 &  
 Dietary exposure in the  
 Netherlands

Bianca van de Ven  
 RIVM, Netherlands

Mineral oils | 27 Mrc 2019



**What is mineral oil?**

Petroleum fraction with high boiling point (BP > 350 ° C)

Residue after distillation of gas, kerosene, petrol, diesel, solvents

Waxes and paraffins, raw material for:

Lubricating oils, hand cream, food additives, etc.

Chemically

Formula hydrocarbons:  $C_xH_y$ , (sometimes with N, S)

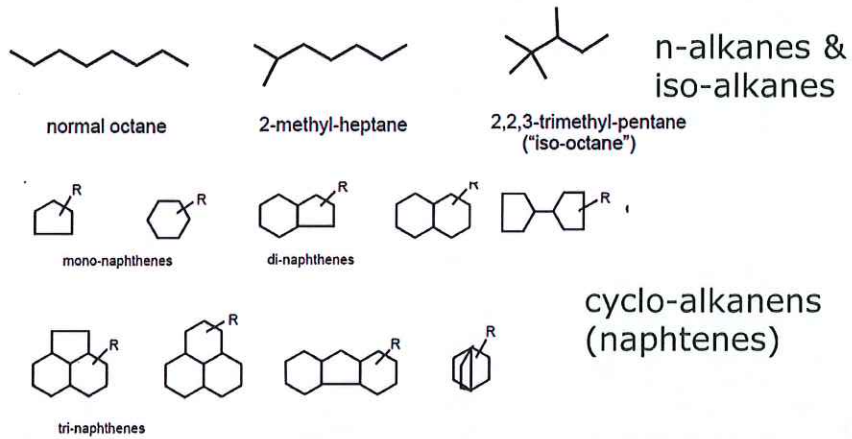
C10 - C50

2 fractions: - saturated (MOSH)  
 - aromatic (MOAH)

2



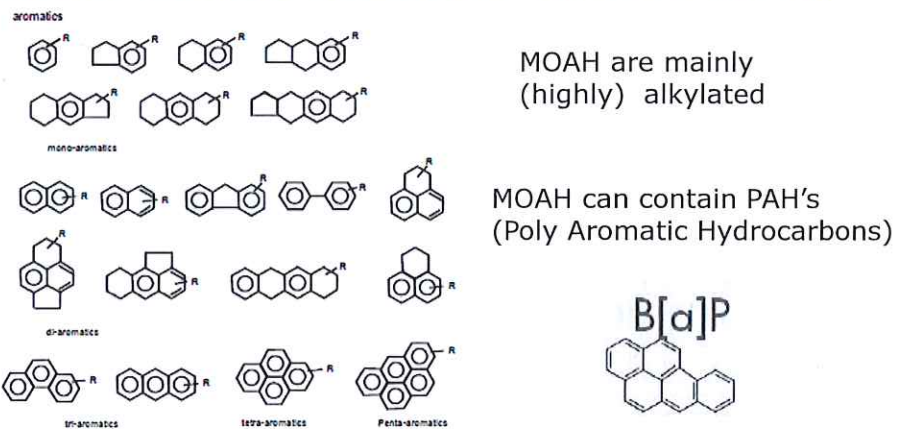
## MOSH - Mineral Oil Saturated Hydrocarbons



3



## MOAH: aromatic fraction (15-30% of total MOH)

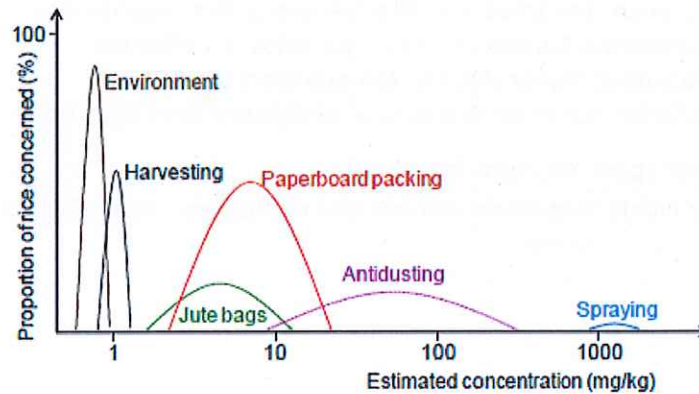


4



## Contamination sources in rice

From EFSA report:



5



## Toxicology MOSH (EFSA 2012)

- No acute toxicity
- No mutagenicity, nor carcinogenicity
- Accumulation in liver, spleen, lymph nodes and fat (C16-C40)
- Rats: microgranulomas in the liver; and inflammation
  
- Immunotoxicity?
- Relevance of effect for humans?

Margin of Exposure (MOE) approach; Tox. Reference Point (RP):

- NOAEL of 19 mg/kg bw/day (MOSH)
- NOAEL of 45 mg/kg bw/day (MOSH of white mineral oils)

6



## MOSH – new data on accumulation

Repeated oral dose, 90 days in rat:

- Accumulation: branched /iso alkanes and cyclics (naphthenes)
- Microgranuloma formation: wax / paraffins (n-alkanes)
- F344 rats have higher [MOSH] (blood&liver) than SD rat
- Accumulation not proportional to administered dose (saturation)

Human-liver (post mortem biopsies):

- Mainly highly isomerised alkanes and naphthenes; peak C25-C28
- Hardly any n-alkanes
- No microgranulomas or inflammation (but exposure unknown!)

7



## MOSH - new data on immunology

MOSH exposure, irrespective of mixture tested:

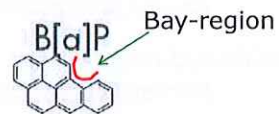
- No impact on the immune response following antigen challenge
  - Did not induce arthritis by the oral route
- > No indication of immunologic effects after oral exposure to MOSH

8



## Toxicology MOAH (EFSA 2012)

- No acute toxicity
- No accumulation after chronic intake
- MOAHs from unrefined oils induce tumors
- PAH's: 3-7 rings are mutagenic, peak at 5 rings
- Alkylation causes steric hinderance



- Methylation sometimes enhances genotoxic potency
- Mixture toxicity of MOAH -> no marker molecules
- No dose-response data -> no tox. Reference Point

9



## MOAH – New toxicological data

*One in vitro* study -> indication that MOAH could potentially be endocrine disruptors

- No in vivo dose response data available
- No quantitative risk assessment possible

10



## Risk assessment MOAH - Qualitative

Refined mineral oils

Hydrogen (H) treated → saturation aromatic rings → naphthenes and lower number of aromatic rings; e.g. printing inks > 98% 1-2 rings MOAH

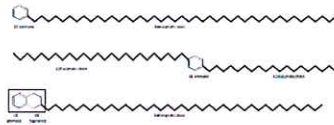
Crude or insufficiently refined mineral oils

Carcinogenic properties. e.g. Batching oil in jute bags

Combusted mineral oils:

Formation of pyrogenic MOAH, a.o. PAH's → potentially genotoxic

-> Not all MO sources contain MOAH that are mutagenic



MOAH in microcrystalline wax



## Exposure Dutch population (background)

Diet: Dutch Survey on Food Consumption data  
 Occurrence: Foodwatch data (NL-dry food, chocolate), EFSA 212 (other products)  
 PD / RP: 19 mg/kg bw/d

Table 4. Margins of exposure (MOEs) calculated for the exposure to MOSH (median and high (P95) consumption)

Population	Exposure <sup>1</sup> (mg/kg bw/day)		MOE <sup>2</sup> (NOAEL <sup>3</sup> : 19 mg/kg bw/day)	
	P50	P95	P50	P95
2-6 years	0.098	0.21	190	90
7-69 years	0.042	0.12	450	160



## NOAEL, TDI, ADI, MOE, a.f.

NOAEL = No Observed Adverse Effect Level in animal study  
= Dose right below LOAEL (Lowest-OAEL)

TDI = Tolerable Daily Intake (in mg/kg bw/d)

MOE = Margin of Exposure

a.f. = assessment factors / uncertainty factors / safety factors

- interspecies, intraspecies
- for quality of database
- for study duration
- for nature and severity of effect

a.f. = af1 x af2 x af3 x af4 x af5



## MOE approach versus TDI

### Derive TDI

- Select lowest NOAEL
- Determine a.f

TDI = NOAEL/a.f.

Dietary intake < TDI?

Yes: Nice!

No: possibly of concern

### Use MOE approach

- Determine intake
- Select lowest NOAEL

MOE = NOAEL/intake

MOE > a.f.?

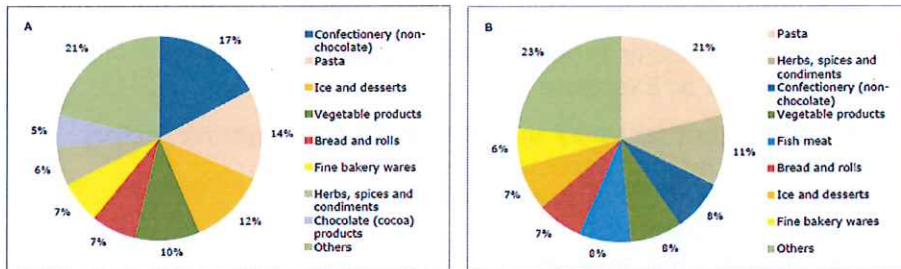
Yes: Nice!

No: possibly of concern



## Exposure Dutch population

Contribution (%) of food groups to the total exposure to MOSH



-> Diffuse exposure

-> Single product with highest contribution: white pasta

15



## Contribution of paperboard packaged dry food

MOSH and MOAH from paperboard packaged dry food

- Pasta, rice, cereals, chocolate sprinklers etc.
- Exposure mainly due to intake of pasta
- Mean contribution (P50): 2%
- High consumers of dry food (P95): 18%

-> Contribution of dry food packaged in paperboard is limited compared to the total intake of MOSH and MOAH

16





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

**Mineral oils in food; a review of  
toxicological data and an assessment of  
the dietary exposure in the Netherlands**

RIVM Letter report 2017-0182  
B.M. van de Ven et al.

Co-authors:

Stella Fragki  
Jan Dirk te  
Biesebeek  
Anton Rietveld  
Polly Boon

<https://www.rivm.nl/bibliotheek/rapporten/2017-0182.pdf>



## Conclusions

### Toxicology – new data

- Oral exposure seems not to induce immunotoxicity
- Liver granuloma's from 'Relevant?' to: "Relevant??"

### Risk assessment

MOSH: Background intake NL -> no health effects expected

High exposures (bread rolls and grain) -> possibly of concern

MOAH: Source is of importance for risk assessment

First focus: Reduce contamination from crude & combusted oils





DEPARTMENT OF BIOLOGICAL STANDARDISATION, OMCL  
NETWORK & HEALTHCARE (DBO)

EDE/rd

Working document, with no legally binding status,  
intended exclusively for the addressees and their  
associates, under the responsibility of the addressees  
(listed opposite). Level 2

*English / Anglais*

PA/PH/MCA (19) 14

Strasbourg, June 2019

GROUP CD-P-MCA

(COMMITTEE FOR FOOD CONTACT MATERIALS AND ARTICLES / COMITE SUR LES MATERIAUX ET OBJETS  
POUR CONTACT ALIMENTAIRE)

**Communication of the Slovenian delegation of the Council of Europe Committee for food  
contact materials and articles (CD-P-MCA)**

EDQM Scientific Officer: Eugenia Dessipri

**Distribution**  
**For action :**

**For information :**  
CD-P-MCA Committee for food contact materials and articles

The Slovenian delegation of the Council of Europe Committee for food contact materials and articles (CD-P-MCA) would like to inform EC about activities regarding enamel food contact materials that have been performed recently.

In autumn 2018 a survey on current situation in Council of Europe member states regarding vitreous (porcelain) enamels has been carried out. The idea was to collect information on enamel testing (on methodology and testing results) and limits used for evaluation of compliance during 4 years (2015 -2018).

During that time period, food contact enamels were analysed in 7 member states. All together 420 samples were analysed: 24 samples in Austria, 16 in Belgium, 81 in Croatia, 20 in Finland, 2 in France, 208 in Germany and 69 in Slovenia. For Germany, results were compiled for laboratories located in 8 states\*.

Release of aluminium, antimony, chromium, cobalt, copper, iron, magnesium, manganese, molybdenum, nickel, silver, tin, titanium, vanadium, zinc, arsenic, barium, beryllium, cadmium, lead, lithium, mercury and thallium from enamels into simulants was determined. Number of analysed metals is presented in Figure 1.

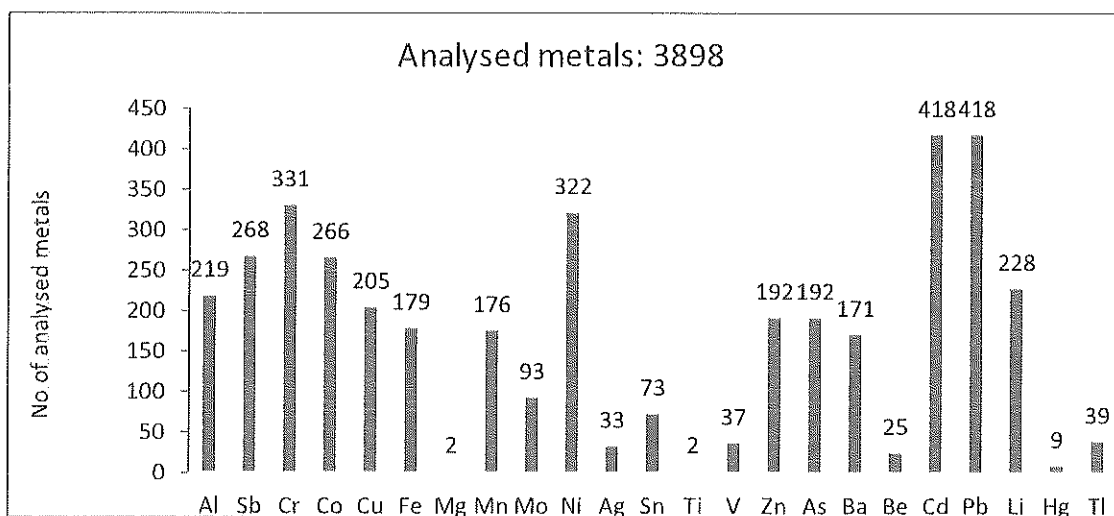
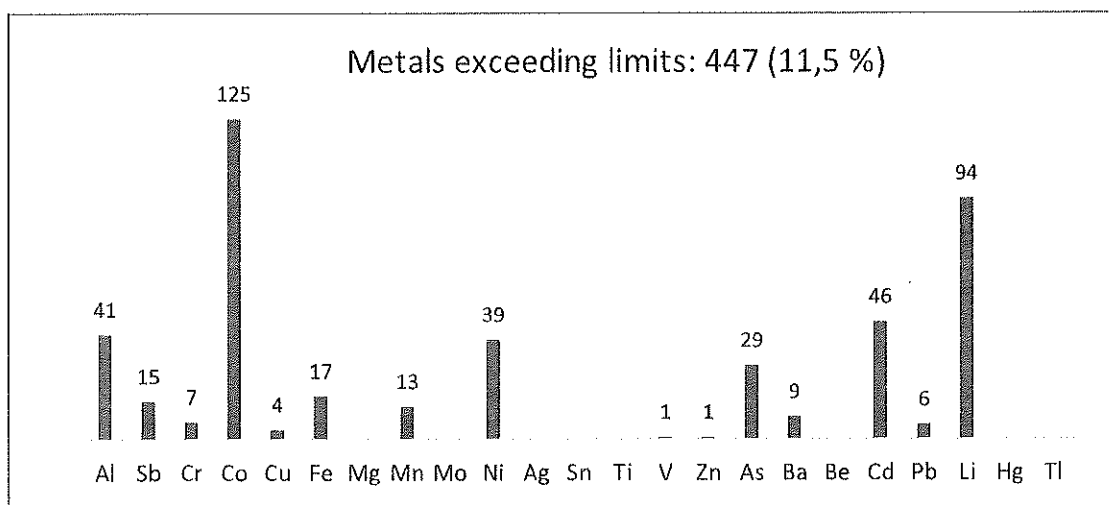


Figure 1. Number of analysed metals which were released from enamel ware during 2015-2018.

Among 3898 analysed metals, 447 metals (11.5 %) exceeded limits used for evaluation of compliance. Metals exceeding limits are presented in Figure 2. Limits were exceeded for various samples: grills, frying pans, bowls, cooking grates, tea pots, casseroles, baking dishes, colanders, pots, mugs, baking trays/sheets, ladles, saucepans.

Several limit values have been used for evaluation of compliance. Laboratories mostly used final or transitional limits from Technical guide on metals and alloys, document prepared by Council of Europe (1, 2). Some laboratories used limit values of European Enamel Association (3), others limit values from national legislation (4) or ISO 4531 (5). Comparison of limit values for the metals released from enamel food contact materials is presented in Table 1.



**Figure 2. Metals exceeding limits: 447 (11,5 %)**

As regards methodology of testing, the collected data show, that different methods were used for release testing as regards simulant and time/ temperature conditions. Laboratories followed the methodology from ceramic food contact materials as required in Ceramic Directive (simulant 4% acetic acid, t/T conditions 24h, 23°C) or methodology from Council of Europe Technical guide for metals and alloys (simulant citric acid 5g/L or artificial tap water, and t/T conditions from Regulation 10/2011 for plastic food contact materials). Additionally, conditions described in ISO 4531 standard (simulant 3% acetic acid and t/T 2h, 70°C or 2h, 95°C) were used as well.

## Conclusions

From the collected data we can conclude that variety of limit values and test conditions were used for assessment of metal release from enamel food contact materials in member states. Results of analysis of different kind of samples indicate that certain proportion of samples exceed the limit values used for assessment. Most issues were related to cobalt and lithium some also with cadmium, aluminium, nickel, arsenic...

The need for harmonisation of limit values and test conditions is clearly evident.

Table 1: Comparison of limit values for release of metals

Element	Release limits from CoE Technical guide for metals and alloys in mg/kg	CoE transitional release limits in mg/kg	Release limits from EEA * guidelines in mg/kg	Release limits from ISO 4531:2018 In mg/kg
Al	5	N/A	N/A	5
Sb	0,04	0,2	0,04	0,04
Cr	0,25	1,0	0,25	0,25
Co	0,02	0,1	0,25	0,1
Cu	4	N/A	1	4
Fe	40	N/A	N/A	N/A
Mg	N/A	N/A	N/A	N/A
Mn	1,8	N/A	0,6	1,8
Mo	0,12	0,6	0,12	0,12
Ni	0,14	0,7	0,14	0,14
Ag	0,08	N/A	N/A	0,08
Sn	100	N/A	N/A	N/A
Ti	N/A	N/A	N/A	N/A
V	0,01	0,05	N/A	0,01
Zn	5	N/A	7	5
As	0,002	0,01	N/A	0,002
Ba	1,2	N/A	1,2	1,2
Be	0,01	0,05	N/A	N/A
Cd	0,005	0,02	0,005	0,005
Pb	0,01	0,04	0,01	0,01
Li	0,048	N/A	0,6	0,48
Hg	0,003	0,015	N/A	N/A
Tl	0,0001	0,0005	N/A	N/A

- Now replaced by ISO 4531:2018

## References:

1. Council of Europe Metals and alloys used in food contact materials and articles A practical guide for manufacturers and regulators, available online: <https://www.edqm.eu/en/food-contact-materials>

2. Letter EDQM sent to national authorities concerned with the surveillance of food contact materials in 2013 regarding specific release limits during the transitional period (Council of Europe, EDQM, RZ/PH/2013-06790L, SBA/mfs,18.11.2013)
3. EEA association, document available online: [https://www.european-enamel-authority.org/sites/default/files/EEA\\_guideline\\_1001.pdf](https://www.european-enamel-authority.org/sites/default/files/EEA_guideline_1001.pdf)
4. Limit values from national legislation available online:  
[https://ec.europa.eu/food/sites/food/files/safety/docs/cs\\_fcm\\_non-harmonised-summary\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_non-harmonised-summary_en.pdf)  
(collected in 2014);  
<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study>
5. EN ISO 4531(2018) Vitreous and porcelain enamels- Release from enamelled articles in contact with food- Methods of test and limits





# Release of metals from enamels

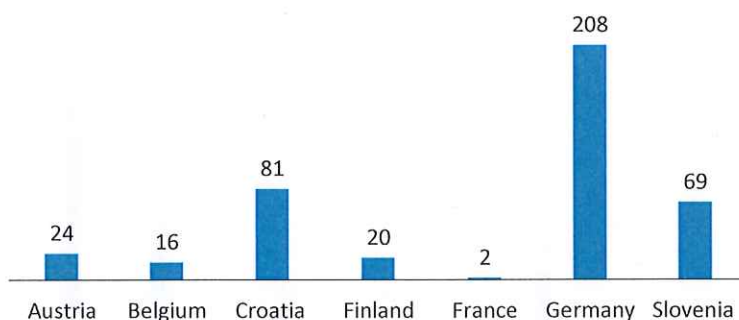
V. Golja<sup>1</sup>, A.Zorič<sup>2</sup>

<sup>1</sup>National Institute for Public Health Slovenia,

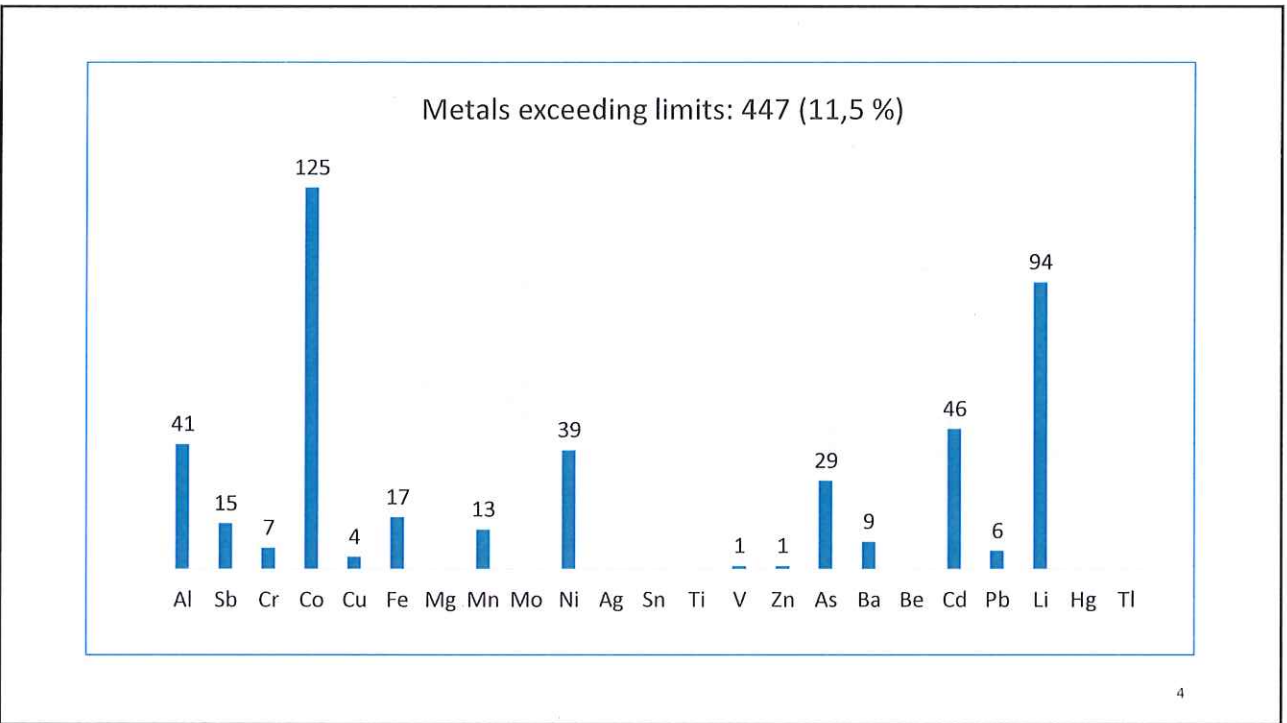
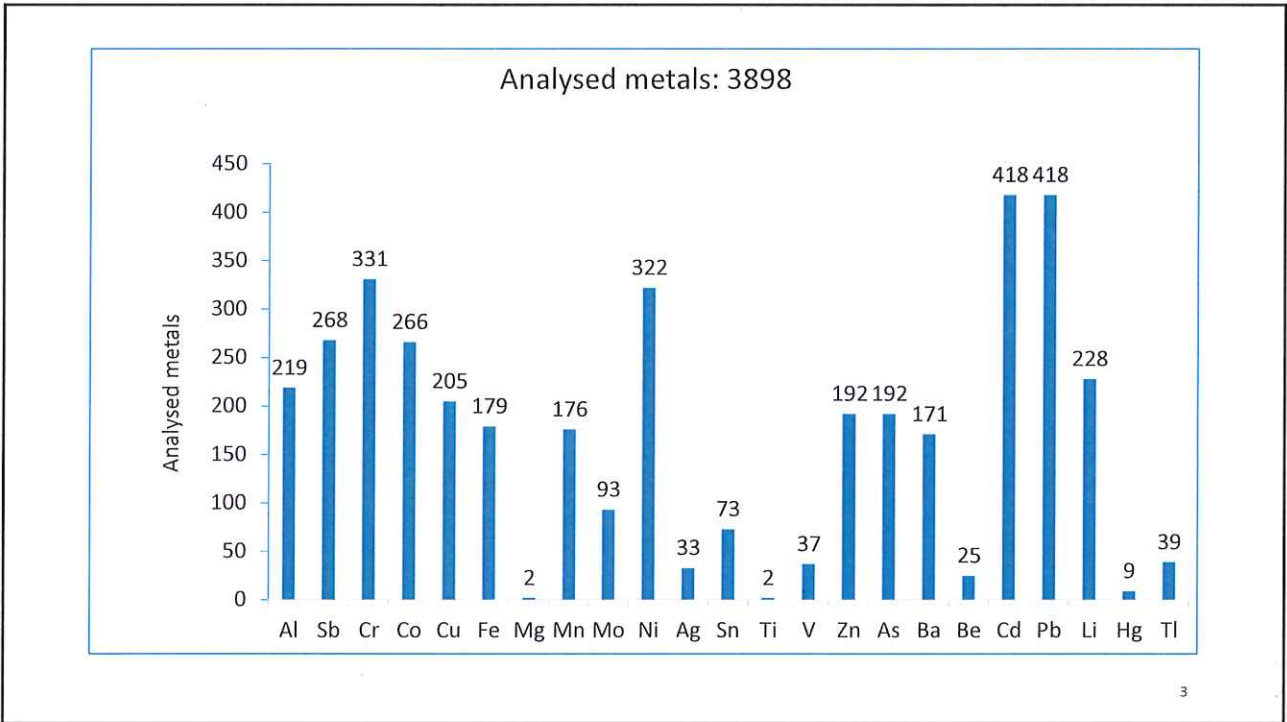
<sup>2</sup>National Laboratory of Health, Environment and Food Slovenia



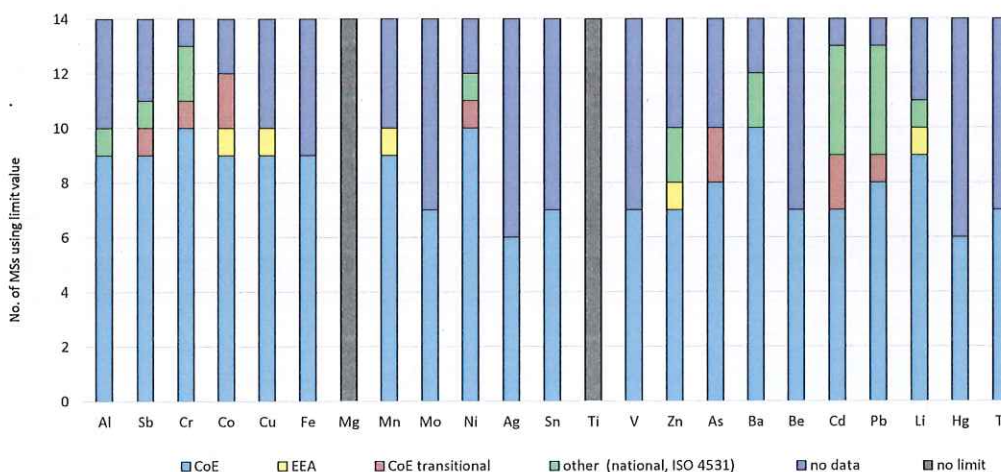
- 16 MS responded
- In 2015-2018 enamels were analysed in 7 MS (420 samples)



- No analysis in that time period in other 9 MS (Cy, Gr, L, NL, E, S, CH, UK, Taiwan)
- Germany – compiled results of 8 states



## Limit values used for conformity assesment



## Metals exceeding limits & values used for conformity

Co (125) 28,0 %	VALUE USED	
	0,25 mg/kg	D <sub>Bav</sub> (2)
	0,1 mg/kg	D <sub>NRhineWest</sub> (89), Si (13)
	0,02 mg/kg	A (9), B (5), Hr (1), D <sub>CVUA St</sub> (1), D <sub>Hess</sub> (3), D <sub>Schles-Hol</sub> (1)
?	D <sub>ILC Koblenz</sub> (1)	

Li (94) 21,0 %	VALUE USED	
	0,48 mg/kg	D <sub>NRhineWest</sub> (56)
	0,048 mg/kg	A (9), B (2), Hr(1), D <sub>Hess</sub> (2), D <sub>CVUA St</sub> (2), Si (15)
?	D <sub>ILC Koblenz</sub> (7)	

## Metals exceeding limits & values used for conformity

Cd (46) 10,3 %	VALUE USED	
	0,02 mg/kg	D <sub>NRhineWest</sub> (28), Si (7)
	0,005 mg/kg	D <sub>Hess</sub> (3)
	0,07 mg/dm <sup>2</sup>	D <sub>Lune</sub> (7)
	0,1 mg/dm <sup>2</sup>	Fin(1)
Al (41) 9,2 %	VALUE USED	
	5 mg/kg	A (7) , B (1), D <sub>Sax</sub> (5), D <sub>NRhineWest</sub> (23), D <sub>Hess</sub> (5)

7

## Metals exceeding limits & values used for conformity

Ni (39) 8,7 %	VALUE USED	
	0,14 mg/kg	A (3), B (1), D <sub>Hess</sub> (1), D <sub>CVUA St</sub> (1), Si (4), D <sub>Lune</sub> (7)
	0,7 mg/kg	D <sub>NRhineWest</sub> (21)
	2 mg/dm <sup>2</sup>	Fin(1)
As (29) 6,5 %	VALUE USED	
	0,002 mg/kg	A (2) , B (1), D <sub>Lune</sub> (7)
	0,01 mg/kg	D <sub>NRhineWest</sub> (18), D <sub>Sax</sub> (1)

## Metals exceeding limits & values used for conformity

Fe (17)	VALUE USED	
3,8 %	40 mg/kg	B (1), D <sub>NRhineWest</sub> (16)

	VALUE USED	
Sb (15)	0,2 mg/kg	D <sub>NRhineWest</sub> (3)
3,4 %	0,04 mg/kg	B (1), D <sub>CVUA st</sub> (1), D <sub>Lune</sub> (7), Si (3)

9

## Metals exceeding limits & values used for conformity

Mn (13)	VALUE USED	
2,9 %	1,8 mg/kg	B(2), D <sub>NRhineWest</sub> (8), D <sub>Schles-Hol</sub> (1), Si (2)

	VALUE USED	
Ba (9)	1,2 mg/kg	B (2), D <sub>Schles-Hol</sub> (1), Si (3)
2,0 %	1 mg/article	A (3)

10

## Metals exceeding limits & values used for conformity

	VALUE USED	
Cr (7)	1 mg/kg	D <sub>NRhineWest</sub> (3)
1,6 %	0,25 mg/kg	A (2), Si (2)

	VALUE USED	
Pb (6)	0,04 mg/kg	D <sub>NRhineWest</sub> (3)
1,3 %	0,01 mg/kg	D <sub>Hess</sub> (1), Si (2)

11

## Metals exceeding limits & values used for conformity

	VALUE USED	
Cu (4)	4 mg/kg	D <sub>NRhineWest</sub> (3), Si (1)
0,9 %		

	VALUE USED	
V (1)	0,01 mg/kg	B (1)
0,2 %		

	VALUE USED	
Zn (1)	3 mg/article	A (1)
0,2 %		

12

### Colour of some samples with metals exceeding limits

Al	X	x		X					
Sb	X				X				
Cr	X								
Co	X	x	X						X
Cu	X								
Fe	X				X				
Mn	X				X				
Mo									
Ni	X								
V	X								
Zn	X								
As	X								
Ba					X				
Be									
Cd	X	x		X	X	X			
Pb	X								
Li	X	x			X		X	X	

- the colour was not reported by all MS
- $D_{NRhineWest}$ : significant/high release of metals often occurs with black enamelled products and with thin enamel layers

13

### Metals **not** exceeding limits & values used for conformity

- Not exceeding values used for conformity:  
Mg, Mo, Ag, Sn, Ti, Be, Hg and Tl
- In all cases (except for Ti and Mg with no limit values) CoE limit were used

14

## Overall migration, **not** exceeding conformity values

OM (82)	VALUE USED	
	60 mg/kg	Si (1)
	50 mg/dm <sup>2</sup>	Hr (81)

15

Element	Release limits from CoE Technical guide for metals and alloys in mg/kg	CoE transitional limit values in mg/kg	Release limits from EEA guideline in mg/kg	ISO 4531:2018 release limit values in mg/kg
Al	5		N/A	5
Sb	0,04	0,2	0,04	0,04
Cr	0,25	1,0	0,25	0,25
Co	0,02	0,1	0,25	0,1
Cu	4		1	4
Fe	40		N/A	N/A
Mg	N/A		N/A	N/A
Mn	1,8		0,6	1,8
Mo	0,12	0,6	0,12	0,12
Ni	0,14	0,7	0,14	0,14
Ag	0,08		N/A	0,08
Sn	100		N/A	N/A
Ti	N/A		N/A	N/A
V	0,01	0,05	N/A	0,01
Zn	5		7	5

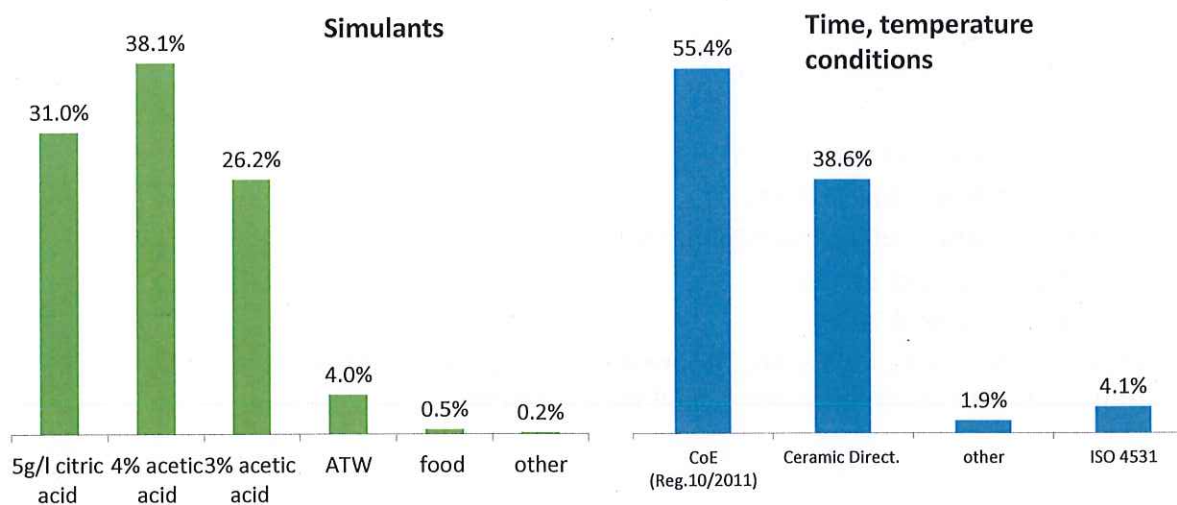
16



Element	Release limits from CoE Technical guide for metals and alloys in mg/kg	CoE transitional limit values in mg/kg	Release limits from EEA guideline in mg/kg	ISO 4531:2018 release limit values in mg/kg
As	0,002	0,01	N/A	0,002
Ba	1,2		1,2	1,2
Be	0,01	0,05	N/A	N/A
Cd	0,005	0,02	0,005	0,005
Pb	0,01	0,04	0,01	0,01
Li	0,048		0,6	0,48
Hg	0,003	0,015	N/A	N/A
Tl	0,0001	0,0005	N/A	N/A

17

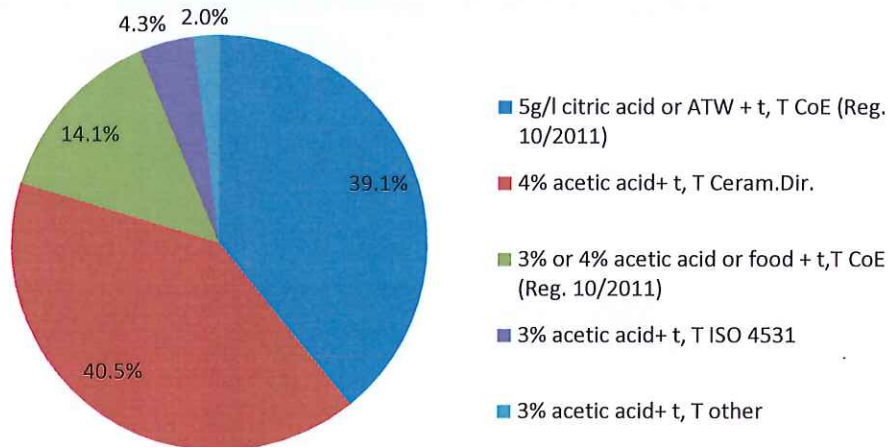
## Test conditions (1)



18

## Test conditions (2)

Simulant + time&temperature combination



Some MS determined metal concentration in 3rd migration test (A, Hr,  $D_{Hess}$ ,  $D_{NRhineWest}$ ,  $D_{Luner}$ , Si), for others it is not clearly stated if consecutive tests were performed.

19

- $D_{NRhineWest}$  performed interesting testing: the same samples with significant release were tested with various simulants and test conditions (consecutive tests):

- ATW 1h 100°C,:
- 4% acetic acid 24h room T,
- 0,5 % citric acid 2 h 70°C,
- 0,5 % citric acid 2 h 100°C and 1h 100°C,
- 3% acetic acid 2 h 70°C,
- 3% acetic acid 2h, 95 °C,

Pb, Cd, Cr, Ni, Co, Fe, Al, As, Sb, Li were determined. Exceeding limits in acidic simulants. One sample exceeding limit for As in ATW

20

- Belgium (Heidi Demaegdt, Sciensano)– interesting testing results of 15 enameled samples from the European market (4% acetic acid, 22°C, 24<sup>h</sup>, 3 consecutive migrations with cleaning in between).
- For Be, V, Fe, Zn, Se, Sn and Tl: very low or <LOQ release in all samples.
- For Cr, Cu and Sb elevated values for 2 samples, but still under SRLres.
- For Mo: elevated values for 1 sample, but still under SRLres.
- For Li, Al, Mn, Co, Ni, As, Cd, Ba, Pb and Ti: exceeded in some samples in 1st migration, but 3rd migration was almost always lower than SRLs (except for 1 sample **Li**, 2 samples **Co**, 1 sample **Ni**).

21

## National legislation

- Austria: Ceramic Directive limits for Pb, Cd; additionally limits for Zn, Sb, Ba
- Netherlands: OML, SML for As, Ba, B, Cd, Cr, Co, Hg, Li, Pb, Rb, Se, Sr
- Spain: Ceramic Directive limits for Pb, Cd
- France: draft standard ISO/DIS 4531 for testing and permissible limits for Ag, Ba, Cd, Cr, Co, Cu, Li, Mn, Mo, Ni, Pb, Sb, V, Zn
- Czech Republic
- Italy
- Portugal
- Norway

Data based on:

[https://ec.europa.eu/food/sites/food/files/safety/docs/cs\\_fcm\\_non-harmonised-summary\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_non-harmonised-summary_en.pdf) (as collected in 2014) and communication with MS.

22

## Conclusions

- Variety of analysed samples /metals, limit values used for conformity and test conditions in the MS
- NEED FOR HARMONISATION!
- Most issues with Co and Li (due to the replacement of Ni?)
- Also exceeding limit values: Cd, Al, Ni, As ...

23



DEPARTMENT OF BIOLOGICAL STANDARDISATION, OMCL  
NETWORK & HEALTHCARE (DBO)

EDE/mfs

Working document, with no legally binding status,  
intended exclusively for the addressees and their  
associates, under the responsibility of the addressees  
(listed opposite). Level 2

*English / Anglais*

PA/PH/MCA (18) 12 R2

Strasbourg, May 2019

GROUP CD-P-MCA

(COMMITTEE FOR FOOD CONTACT MATERIALS AND ARTICLES / COMITE SUR LES MATERIAUX ET OBJETS  
POUR CONTACT ALIMENTAIRE)

### **State of work**

EDQM Scientific Officer: Susanne Bahrke

#### **Distribution**

**For action :**

#### **For information :**

CD-P-MCA Committee for food contact materials and articles

## Committee for food contact materials and articles (CD-P-MCA)

State of work

I Ongoing activities, last updated May 2019

CD-P-MCA Activities		Secretariat	Other actors	State of work			Comments		
Activity <sup>1</sup>	Title	Objective(s)	Tasks	Rapporteur/s or interest group	Output + results	Stipulated dates	Current status	Nat. legislation <sup>2</sup>	
A_03	Terms of reference CD-P-MCA 2020-21	Prepare proposals for approval by the Committee of Ministers (CM)	Follow-up	All	ToR 2020-21	Committee of Ministers Dec 2019			Prepare proposals for amendments of current ToR
A_04	Terms of reference (ToR) 2019-20 ad hoc group on printing inks	CD-P-MCA to reassign the tasks	Follow up	BE, CH, CZ, DE, EL, ES, FR, PT, SE, SK, SI, +JRC	ToR 2019-2020	05/2019	Amendments on existing draft	CH	Existing working group continues activities

<sup>1</sup> Activity: type of activity + serial number

A – Administration (e.g. terms of reference) / E – Symposium, training, promotion (event) / M – Monitoring / R – study report or any other report / S – policy or resolution / T – technical standard or guidance document

<sup>2</sup> Non-harmonised food contact materials in the EU: regulatory and market situation – BASELINE STUDY. Final report. Administrative arrangement SANTE/2014/E6/SI2.684014 – C. Simoneau, B. Raffael, S. Garbin, E. Hoekstra, A. Mieth, J. A Lopes, V. Reina, 2016.

CD-P-MCA Activities			Secretariat	Other actors	State of work			Comments	
Activity <sup>1</sup>	Title	Objective(s)	Tasks	Rapporteur/s or interest group	Output + results	Stipulated dates	Current status	Nat. legislation <sup>2</sup>	
R_01	Survey	Evaluation of current state of enamelled FCM	Coordination	SI	Current practice in member states / market situation	05/2019 Presentation of results from survey		AT, CZ, EL, ES, FR, NL	Survey - results collected by January 2019.
S_01	Resolution on food contact materials	Harmonised requirements for materials for food contact	Drafting, translation, legal+linguistic review, coordination	DE	Draft resolution	05/2019	Draft FCM resolution PA/PH/MCA (18) 9 R1 DRT	N/A	To be submitted to CM preferably after finalisation of draft guidance on specific materials (e.g. paper and board).
S_02	Metals & alloys	Revision of existing guidelines	Coordination	BE, DE, EL, FR, IT, NL, SI, SP + JRC  Drafting group: BE, DE, EL, FR, IT, NL	Update technical guidance, ad hoc meetings	05/2019	Agreement for SRLs - Drafting amendments for chapters 2 and 3 ongoing	AT, BE, CH, CZ, EL, FR, HR, IT, NL, SK Standard in FR, SE.	Teleconferences (2) held in March 2019 on SRLs (experts from public sector/drafting group).

CD-P-MCA Activities		Secretariat	Other actors	State of work			Comments		
Activity <sup>1</sup>	Title	Objective(s)	Tasks	Rapporteur/s or interest group	Output + results	Stipulated dates	Current status	Nat. legislation <sup>2</sup>	
T_01	Cork: updating CoE policy statement	Revision of existing documentation	Coordination	Pending	Draft requirements	Not defined	Draft technical guide to be amended PA/PH/EMB (11) 12 R3 +explanatory documentation PA/PH/EMB (17) 36	CZ, FR, HR, IT, NL and SK, Standard in IT, PT.	PT did not assign delegate to the CD-P-MCA – no rapporteur assigned. Moldova to pick up or suspend
T_02	Ion exchange: updating CoE policy statement	Revision of existing documentation	Coordination	<u>BE</u> , ES and FR	Draft requirements	Not defined	Draft guidance under preparation	ES and FR, Standard in FR.	
T_03	Paper & board: updating CoE policy statement	Revision of existing documentation	Coordination	Ad hoc group with experts from <u>AT</u> , <u>BE</u> , <u>CH</u> , <u>CY</u> , <u>CZ</u> , <u>DE</u> , <u>DK</u> , <u>EL</u> , <u>ES</u> , <u>FR</u> , <u>FI</u> , <u>NL</u> , <u>NO</u> + <u>JRC</u>	Draft requirements, ad hoc meetings	05/2019	Draft guidance PA/PH/MCA (19) 8	BE, CZ, DE, EL, FR, HR, IT, NL, PL, SK.	12 <sup>th</sup> meeting 27/03/2019



CD-P-MCA Activities		Secretariat	Other actors	State of work		Comments			
Activity <sup>1</sup>	Title	Objective(s)	Tasks	Rapporteurs/ or interest group	Output + results	Stipulated dates	Current status	Nat. legislation <sup>2</sup>	
T_04	Printing inks: updating CoE policy statement	Revision of existing documentation	Coordination	BE, CH, CZ, DE, EL, ES, FR, PT, SE, SK, SI, - +JRC	Draft guidance on testing, ad hoc meetings	Not defined	Information gathering; peer review planned of multi-analyte method (feasibility phase)	CH, CZ, FR, HR, IT, NL, SK, Draft: DE, Standard in FR.	4th meeting of working group 19 February 2019, Familiarisation samples for Peer-Review distributed
T_05	Coatings and varnishes: updating CoE resolutions + technical documents	Revision of existing CoE technical documents	Coordination	BE, NL	Draft requirements, ad hoc meetings	Not defined	Work initiated at CoE and EFSA	BE, CZ, DE, EL, ES, FR, HR, IT, NL, SK, Standard in DE.	EFSA-partnering grant group – Teleconferences Workshop 16 May 2019
T_06	Compliance work	Draft technical guide on compliance documentation for food contact materials	Coordination	CH	Draft guidance	Not defined	PA/PH/MCA (18) 25 R2	N/A	Complements Resolution on Food Contact Materials
T_07	Enamelled food contact materials and articles	Harmonised requirements for materials for food contact.	Coordination	BE, CZ, DE, FR, SI	Draft requirements, ad hoc meetings.		Revised ToR draft PA/PH/MCA (18) 14	AT, CZ, EL, ES, FR, NL	Collaboration to start depending on EC decision to include

CD-P-MCA Activities		Secretariat	Other actors	State of work			Comments	
Activity <sup>1</sup>	Title	Objective(s)	Tasks	Rapporteur/s or interest group	Output + results	Stipulated dates	Current status	Nat. legislation <sup>2</sup>
								enamels in ceramics legislation.

### II Completed work

Activity <sup>1</sup>	Title	Objective(s)	Secretariat tasks	Rapporteur/s or interest group	Output + results	Final status
A_01	Terms of reference (ToR) 2017-18 ad hoc group on printing inks	P-SC-EMB to assign tasks	Drafting and follow up	All	ToR 2018-19	Approved by the P-SC-EMB (Oct 2016) PA/PH/EMB (16) & FINAL.
A_02	Terms of reference CD-P-MCA 2018-19	Prepare proposals for approval by the Committee of Ministers (CM)	Drafting and follow-up	All	ToR 2018-19	Approved by the Committee of Ministers (Nov 2017) PA/PH/MCA (18) 1.

**III Proposed topics for future work and suspended items**

Activity <sup>1</sup>	Title	Objective(s)	Secretariat tasks	Rapporteur/s or interest group	Output + results	Comments
M_0n	Information on member states activities	Report on recent and scheduled activities	Report	-	-	No interest for the time being.
R_0n	Polymeric materials used for food & pharmaceutical products	Taking stock of relevant regulations, approach comparison, identification of gaps and divergence	Coordination of activities	BE, CH, CZ, ES	ToR for working group; questionnaire; data collection report + conclusions	<ul style="list-style-type: none"> <li>ToR approved by CD-P-SC + ad hoc WG composed</li> <li>Detailed report outlined (drafting suspended)</li> <li>RASFF cases + batch recalls reviewed in 2011-12</li> <li>Summary report on replies to questionnaire</li> </ul>
S_0n	Follow up to EFSA ESCO work	Compile national (positive) lists, keep updated	Coordination			Belgian FCM database; update substance inventories with input from industry?
S_0n	Lead leaching from glass: updating CoE resolutions + technical documents	Review existing CoE resolutions + update technical documents	Coordination	DE	Draft revised documents	Draft revised documents circulated for comments; EC/FCM group currently reviewing EU ceramics regulations (2017/8) with a view including crystal glass in the scope of specific measures.
T_0n	Colourants: updating CoE resolutions + technical documents	Review existing CoE resolutions + update technical documents	Coordination	DE	Draft revised documents	Draft revised documents circulated for comments.

Activity <sup>1</sup>	Title	Objective(s)	Secretariat tasks	Rapporteur/s or interest group	Output + results	Comments
T_0n	Silicones: updating CoE resolutions + technical documents	Review existing CoE resolutions + technical documents	Coordination	CZ (follow up with No, NL and DE)	Draft revised documents	Germany: recommendations
T_0n	Rubber: updating CoE resolutions + technical documents	Revision of existing CoE technical documents	Coordination	BE, NL	Draft requirements, ad hoc meetings	National legislation: AT, BE, CZ, DE, EL, ES, FR, HR, IT, NL, SK. Standard in DE.
T_0n	Guidance on risk assessment	Define material-specific dossier requirements + procedures	Coordination			
T_0n	Advisory group on Substance database	Advice on data, formats and presentation	Coordination	BE, DE	Ad hoc meetings, technical guidance	Due to insufficient participation, this group was not set up.