

Council of Europe activities

on Food Contact Materials

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



HealthCare Activities: Technical Guides - Resolutions & Recommendations

- **Steering Committees and experts** develop guides to ensure quality and good practices & protect consumers, e.g.
 - Safe cosmetics for young children
 - **Metals & alloys used in food contact materials**
 - Guidance on essential oils in cosmetic products
 - Hydrogen peroxide in cosmetic products
 - Safer tattooing: overview of current knowledge and challenges of toxicological assessment
- **Council of Europe Recommendations and Resolutions:**



Adopted by the [Committee of Ministers](#): “ ... Recommends to the governments of member States Parties to the Convention that they adopt legislative and other measures ...”

Food contact materials and articles

- **Steering Committee (2018)** supported by the Secretariat Committee for food contact materials and articles (Partial Agreement) (CD-P-MCA) - ToR renewed every two years.
- **Members:** delegates from the 38 countries of the Pharmacopoeia Convention (27 countries have appointed representatives).
- Rapporteurs assigned to projects (members or participants).
- Plenary sessions: 1-2 times a year, in Strasbourg.
- *Ad hoc* working groups: flexible in time and place; ± 1-2 times a year meetings, teleconferences.
- *Ad hoc* electronic working groups, teleconferences.

FCM Resolution – Guiding Principles / Technical Guides

- **Scope:** all FCM under Regulation (EC) 1935/2004 **which are not covered by specific measures** at the EU level
- **Best practices** to ensure quality and safety:
 - [Principles for the intentional use of substances](#)
 - Compliance documentation and declaration of compliance for all FCM
- Technical guides to cover material-specific issues (restrictions for substances to be used in the manufacture, testing issues, etc)
- Technical guide for compliance documentation and declaration of compliance

Other on-going activities

- Compliance Documentation – Technical guide supplementing the Resolution.
- Paper and Board – Technical guide supplementing the Resolution.
- Printing inks – Peer-review of multianalyte method.
- Enamels – Survey led by Slovenia on current situation in CoE member States.
- Coatings – Follow-up EFSA-FIP taskforce.
- Cork, Ion exchange resins, Printing inks.



Paper and Board: Technical guide

- Substances intentionally used: links to member state^(*) legislations/official recommendations.
- Table with SMLs for certain substances.
- Reference to standards and tests.
- Restrictions for the use of recycled fibres.
 - Functional barrier / absorbent.
 - Reference method for assessing barrier efficiency.
 - 10 ppb migration limit, no CMR, nano.
 - Specific requirements in the compliance documentation and declaration of compliance.

(*) France, Germany, Italy, Netherlands.

Printing Inks: Multi-analyte method peer-review

REGISTRATION FORM: Food Contact Materials Peer review (MCA PEER REVIEW) Programme 2nd Semester 2019

Please complete and return this form to Consumer Health Protection, DBO, EDQM before **26 August 2019**
 by post: EDQM, 7, Allée Kastner, CS30026 F-67081 Strasbourg
 by fax: +33 (0)3 88 41 27 71
 by email: consumer.health@edqm.eu

REGISTRATION DETAILS

PARTICIPANT DETAILS* (Delivery address)		INVOICING DETAILS (if different from participant/delivery details)	
First Name		First Name	
Last Name		Last Name	
Company/ Institution		Company/ Institution	
Name of Unit/ Section (to be mentioned in the attestation of the participant)		Address	
Address (No PO Boxes)			
Postcode		Postcode	
Town		Town	
Country		Country	
VAT No (EU only)		VAT No (EU only)	
Tel		Tel	
Fax		Fax	
E-mail		E-mail	
Purchase Order Reference (to be mentioned on the invoice)			

*Please note that all related information, documentation or material (e-mails, protocols, samples, reports, attestations of participation) will be sent to the above-mentioned registered participant at the above-mentioned address.

MCA PEER REVIEW n°	MCA PEER 001
Name of Study	Printing Inks
Date of sample shipment	01/10/2019
Deadline for result submission	05/12/2019
Participation	<input type="checkbox"/> YES <input type="checkbox"/> NO
Our laboratory will report results following the method(s) of extraction	<input type="checkbox"/> Carrez <input type="checkbox"/> QuEChERS <input type="checkbox"/> SiveEt
Our laboratory will report results following the method(s) of detection	<input type="checkbox"/> LC/MS-MS <input type="checkbox"/> GC/MS-MS <input type="checkbox"/> GC-MSD

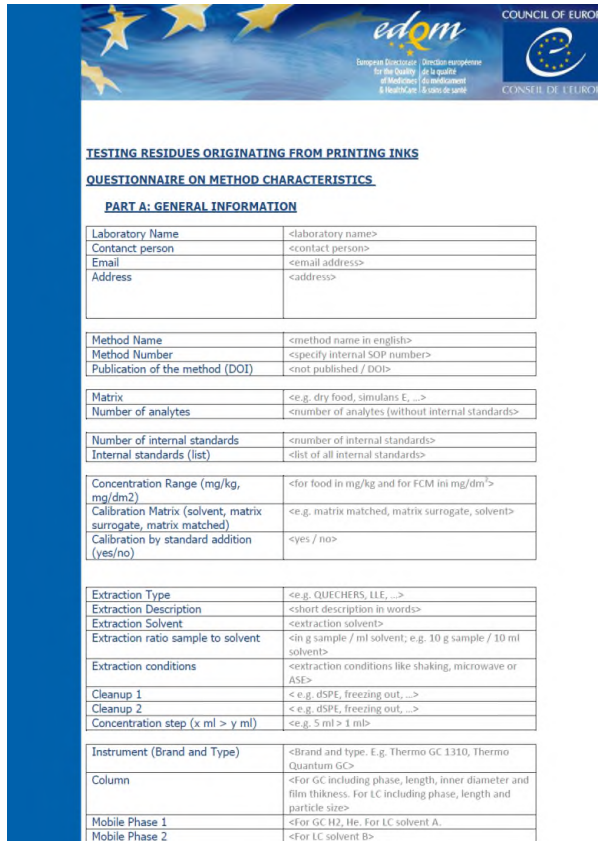
FEES: MCA PEER 001 samples will be provided free of charge.

Date	Name	Signature

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- Study's scope: determination of interlaboratory reproducibility (precision)
- 14 laboratories
- Both GC and LC based analysis
- Analytes: 6 photoinitiators, 3 degradation products, 1 plasticiser
- Matrices: 95% EtOH, dry food (flour or ground baking product)
- Common extraction/purification step

Selection / Development of the method



TESTING RESIDUES ORIGINATING FROM PRINTING INKS
QUESTIONNAIRE ON METHOD CHARACTERISTICS
PART A: GENERAL INFORMATION

Laboratory Name	<laboratory name>
Contact person	<contact person>
Email	<email address>
Address	<address>
Method Name	<method name in english>
Method Number	<specify internal SOP number>
Publication of the method (DOI)	<not published / DOI>
Matrix	<e.g. dry food, simulans E...>
Number of analytes	<number of analytes (without internal standards)>
Number of internal standards	<number of internal standards>
Internal standards (list)	<list of all internal standards>
Concentration Range (mg/kg, mg/dm ²)	<for food in mg/kg and for FCM in mg/dm ² >
Calibration Matrix (solvent, matrix surrogate, matrix matched)	<e.g. matrix matched, matrix surrogate, solvent>
Calibration by standard addition (yes/no)	<yes / no>
Extraction Type	<e.g. QUECHERS, ILE...>
Extraction Description	<short description in words>
Extraction Solvent	<extraction solvent>
Extraction ratio sample to solvent	<in g sample / ml solvent; e.g. 10 g sample / 10 ml solvent>
Extraction conditions	<extraction conditions like shaking, microwave or ASE>
Cleanup 1	<e.g. dSPE, freezing out...>
Cleanup 2	<e.g. dSPE, freezing out...>
Concentration step (x ml > y ml)	<e.g. 5 ml > 1 ml>
Instrument (Brand and Type)	<Brand and type. E.g. Thermo GC 1310, Thermo Quantum GC>
Column	<For GC including phase, length, inner diameter and film thickness. For LC including phase, length and particle size>
Mobile Phase 1	<For GC H ₂ , He. For LC solvent A.>
Mobile Phase 2	<For LC solvent B>

- Questionnaire for existing methods.
- Optimisation of GC-MS/MS and LC-MS/MS detection parameters.
- Feasibility study (May 2019): analytes in 95 % ethanol (12 laboratories participated).
 - 10 µg/L achievable LOD
 - linearity > 0.99
 - mean recoveries 95 – 120 %
 - RSD < 20 %
- Extraction procedure from dry food
 - Carrez and QuEChERS based - comparison

Thank you for your attention

