Printing Inks
in the Council of Europe

Eugenia Dessipri, PhD

General Chemical State Laboratory, Athens, GREECE

Susanne Bahrke, PhD

European Directorate for the Quality of Medicines & Health Care, Council of Europe.

Council of Europe (CoE) & FCM

1959: Partial Agreement (18 Member States) in the Social and **Public Health** Field.

Resolutions accompanied by Technical Guidelines.

2007: Memorandum of Understanding between EU & CoE 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

2008: The Council of Europe Committee of Ministers decided to dissolve the Partial Agreement and to transfer the activities related to cosmetics and food contact materials to the EDQM.

EDQM / P-SC-EMB

EDQM = European Directorate for the Quality of Medicines & **Health Care** European Pharmacopoeia

P-SC-EMB = Committee of Experts on Food Contact and WG

- Open to 37 countries + EU incl. EFSA, JRC, + observers
- Plenary sessions: 2 times a year, in Strasbourg
- Meeting working groups: flexible in time and place; ± 1-2 times a year
- Framework Resolution for food contact materials: requirements that are applicable to all materials, which are not subject to any specific legislative measures at the European level.
- Review of previously published technical guidelines.

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

Policy Statement on Packaging Inks (Vs. 2/ 10-10-2007)

The following documents are part of the Council of Europe's policy statement concerning packaging inks applied to the non-food contact surface of food packaging:

- Resolution ResAP (2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs
- Technical document No. 1: Requirements for the selection of packaging ink raw materials applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs (Version 1, 21.12.2006)
- Technical document No. 2, Part 1: Good Manufacturing Practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging and articles intended to come into contact with food (prepared by CEPE)
- Technical document No. 2, Part 2: Code for Good Manufacturing Practices for flexible and fiber-based packaging for food (prepared by FPE in co-operation with CITPA)
- Technical document No. 3: Guidelines on test conditions for packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

Ad Hoc Working Group (2012-2013)

- Aim: Review of the Resolution
- Last meeting: March 2013

  NRL participation – opportunity for more work on technical document No. 3

- Bilateral Collaboration Switzerland/ Germany

  Substances used in printing inks
  PA/PH/EMB (12) 13 R

Document PA/PH/EMB (13) 16

- **Methods of analysis**

There are no specific international standards for packaging inks dealing with determination of ink substances. The progress in chemical analysis is so rapid that any method may be considered obsolete after a limited number of years. It is therefore recommended that the reader search the literature in order to find an appropriate method. Special attention should be paid to the performance characteristics (trueness and precision) at the specified limit.

Specific Challenges

- Inks are applied to all food contact materials – different technologies
- There are more than 5,000 substances included in ink formulations

At Present:

- Surveys performed in many countries (plastics/paper)
- Publications on methods and reviews
- A lot of know-how in industry
- Existing networks of laboratories

P-SC-EMB Survey on Printing Inks

- Review published surveys from Germany and UK + literature + RASFF
- Compose Excel with 99 compounds – candidate list. MS were asked to pick compounds of their priority interest and add other as necessary.
- 6 Countries responded to the survey request: France, Croatia, Austria, Slovenia, Switzerland and Greece.
- Compounds were ranked based on number of countries that expressed interest. For Germany and UK use published results.
- 46 compounds with score higher or equal to 2 (more than 1 country indicating interest).
- Five new compounds were added.
- France suggested the formation of a working group.

- **Terms of Reference (October 2016) PA/PH/EMB (16) 8 FINAL**: focus on analytical issues related to the examination of compliance of printed food contact materials with Regulation EC No. 1935/2004.
- December 2016: EC announced its intention:

  → harmonised legislation for "Printed FCM" by mid 2018
- January 2017: EC will not mandate JRC on analytical issues until mid 2018. Work performed at the ad hoc WG of the CoE is welcome.
- March 2017: call for appointment of experts.
  - Belgium, France, Germany, Greece, Slovak Republic, Spain, Switzerland
  - JRC, EFSA
- May 11, 2017: first meeting

Work in progress (1)

Substances and mixtures that are frequently used in inks, and that release contaminants that raise toxicological concerns:

- **Photoinitiators/ Decomposition products**

→ PIs currently used by industry listed together with their corresponding decomposition products and physico/chemical properties (decisive for analytical method selection) – (Germany, Spain)

- Primary Aromatic Amines
- Plasticisers
- Residual monomers
- Residual solvents
- Antioxidants and decomposition products
- Mineral Oils

Work in progress (2)

Collect analytical data from relevant surveys carried out by member States on potential migrants

Collect literature and share on the EDQM extranet .

Prepare Template:

- Instrumentation used – all relevant information
- Determination in food: Extraction/Purification procedure

Photoinitiators: a food safety review

Miguel Angel Lago[a], Ana Rodríguez-Bernaldo de Quirós[a], Raquel Sendón[a], Juana Bustos[b], María Teresa Nieto[b] & Perfecto Paseiro[a]

Table 2: HPLC-DAD/FLD methods for photoinitiator analysis.

Method	Photoinitiators	Detector parameters	Analytical column	Mobile phase	Type of Sample	Extraction procedure	Reference
HPLC-DAD/FLD	II: 2-ITX	DAD: 260nm FLD exc: 272nm FLD em: 440nm	LC-PAH Supelcosil (250mm x 4.6mm i.d.; 5µm particle size)	A: H_2O B: AcN Isocratic	Food FCM	LLE (QuEChERS)	Rothembacher and others 2007
	I: MMMP II: ITX Amine syn: EDB	DAD: 260nm FLD exc: 264nm FLD em: 440nm	Luna C18 (2) (100mm x 2mm i.d.; 3µm particle size)	A: H_2O B: AcN Gradient	Food	LLE (QuEChERS)	Jung and others 2010
HPLC-DAD	I: HCPK, DMPA, MMMP II: BP, ITX Amine syn: EHA	HCPK: 246nm DMPA, BP: 256nm MMMP: 306nm EHA: 310nm ITX: 386nm	Kromasil 100 C18 (150mm x 4mm i.d; 5µm particle size)	A: H_2O B: AcN Gradient	Food FCM	LLE	Sanches-Silva and others 2008a
	I: HCPK, DMPA, MMMP II: BP, ITX Amine syn: EHA	HCPK: 246nm DMPA, BP: 256nm MMMP: 306nm EHA: 310nm ITX: 386nm	Kromasil 100 C18 (150mm x 4mm i.d; 5µm particle size)	A: H_2O B: AcN Gradient	Food Simulants	Direct Injection	Sanches-Silva and others 2009
	II: BP	256nm	Kromasil 100 C18 (150mm x 4mm i.d; 5µm particle size)	A: H_2O B: AcN Gradient	Food FCM	LLE	Pastorelli and others 2008
	I: HCPK, DMPA, MMMP II: BP, ITX Amine syn: EHA Cat: BIS, THIO	—	CN Nucleosil 100-5 (250mm x 4.6mm)	A: H_2O (TFA/TBAP) B: MeOH C: AcN Gradient	Food Simulants	SPE	Papilloud and Baudraz 2002a, 2002b
	I: HCPK II: BP, ITX Amine syn: EDB, EHA	HCPK: 245nm BP, ITX: 254nm EDB, EHA: 310nm	Luna C18 (250mm x 4.6mm i.d.; 5µm particle size)	A: H_2O B: MeOH Gradient	Food	1st LLE 2nd SPE	Sagratinit and others 2008
	I: HCPK, DMPA, MMMP II: BP, ITX Amine syn: EHA	HCPK: 246nm DMPA, BP: 256nm MMMP: 306nm EHA: 310nm ITX: 386nm	Kromasil 100 C18 (150mm x 4mm i.d; 5µm particle size)	A: H_2O B: AcN Gradient	Food FCM	LLE	Sanches-Silva and others 2008b, 2008c
	II: 2-HBP, 4-HBP, 4-MBP, MBB, DEAB, PBZ, BP	2-HBP, 4-HBP, 4-MBP, MBB, DEAB, BP: 254nm	Kromasil 100 C18 (250mm x 4mm i.d; 5µm	A: H_2O B: AcN	Food FCM	LLE	Rodríguez-Bernaldo de Quirós

Future Work (1)

- Gather and reference relevant standards.
- Organize interlaboratory validation of non-standardized method:

  → photoinitiators in cereals?

– Suggested method from Germany (instrumentation: GC-MS)

Future Work (2)

- Need for development of a **strategy** for the comprehensive analysis of printed FCM.
- Screening methods are essential.
- Involves research that needs funding.
- Start with an outline of a guidance document that will make clear the specific needs where further research/funding is necessary.