



European Commission activities on Printed Food Contact Materials

Jonathan BRIGGS
DG SANTE

FIP scientific network for the cooperation and harmonisation of risk assessment of FCM, the 'EFSA FCM Network' meeting
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This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

JRC 'Baseline' study

Findings on printing inks



- **Types of printing inks**
 - Low migration UV curing
 - Low migration EB curing
 - Conventional oleo-resins
 - Low migration water-based coatings
- **Different types of substances used in excess of 5000**
 - Colourants
 - Binders
 - Solvents
 - Additives
- **Majority not intended to be in direct contact with food**

JRC 'Baseline' study

Findings on printing inks cont.

- **National rules and tools**

+ve list	-ve list	SMLs	OML	Limits for substance quantity	DoC and SD	Basis for sanctions	Basis for enforcement
CH, CoE, DE*, FR, NL, SK	CoE, CZ, HR	CH, CoE, DE*, FR, NL	FR	CH, CoE, CZ, FR, (HR), NL, RO, SK	DE*, FR, IT, Norden, RO	DE*, IT	CoE, Norden

* Draft

- **GMP appears relatively well implemented**
 - Norden
 - EuPIA sector specific guidance
- **Printing ink sector also has further guidance**
 - Inventory lists, information documents

JRC 'Baseline' study

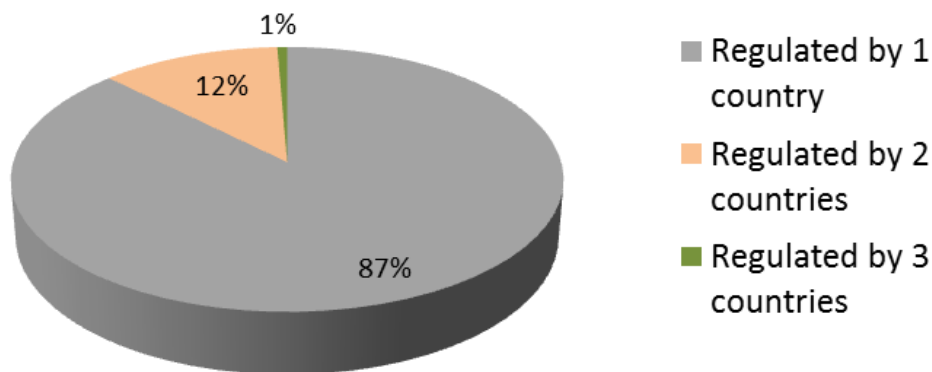
Findings on printing inks cont.

- **Main positive list is Swiss Ordinance (2009)**
- **EFSA ESCO list established 986 authorised substances for which a risk assessment had been undertaken**
- **JRC study added substances including from CoE list**
 - Most substances regulated only by CH 4559 (85%)
 - CoE 831 substances
 - France 43 substances
 - NL 17 substances,
 - SK 15 substances
- **621 substances regulated by two countries; 34 by three**
- **Absence of standards available at EU level**
 - Some at national level (France)

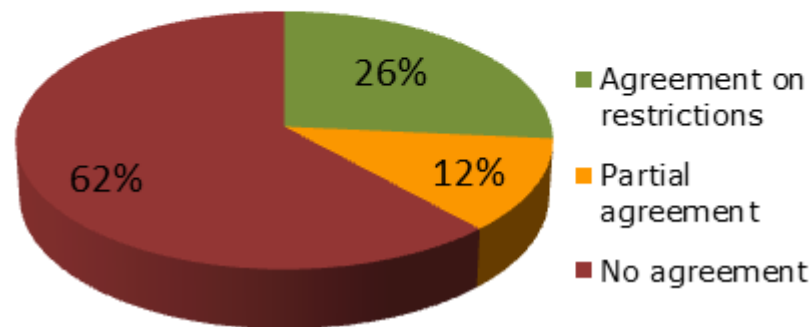
JRC 'Baseline' study

Findings on printing inks cont.

Convergencies of substances for inks



Harmonisation of restrictions regulated by 3 countries for inks



Commission initiative on Printed FCMs

Background and rationale

- **Health concerns outlined – JRC work on PAAs published in 2016**
 - FOOD ADDITIVES & CONTAMINANTS: PART A, 2016 VOL. 33, NO. 6, 1072–1079
- **German notification on printed FCMs summer 2016**
- **Detailed opinions and comments from MSs**
- **Issues highlighted in JRC baseline report**

Progress to date

- **Preparatory work has started**
 - internal procedures + options
 - first consultation with industry on present rules
 - decision to cover printed FCM – not printing inks


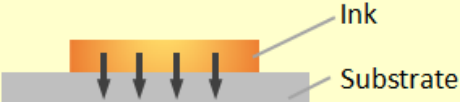
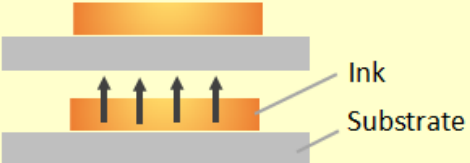
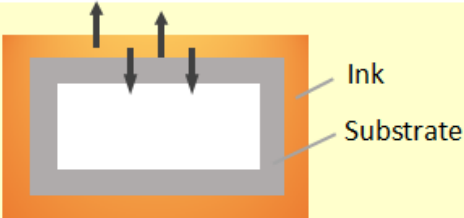
Commission initiative on Printed FCMs

Scope

- **Printed food contact materials (p-FCMs)**
= printing inks + food contact materials that are printed
- **Printing is applied on substrates**
 - Substrates are covered with respect to the applied inks
 - Verification of compliance on substrate
- **Other matters regarding scope addressed later**
 - Different printing techniques (e.g. thermal paper)
 - Dyes, colourants
 - Processing aids for printing (e.g. mineral oil)

Printed FCMs

What is migration?

1	Direct Migration Direct migration from print to the food, in situations where the food is in direct contact with the print	
2	Through Migration Penetration through the substrate to the reverse side of the print	
3	Set-off Migration Set-off from the print to the reverse side while being stored in a pile or reel	
4	Gas Phase migration Volatilisation and condensation of components after heating	

Example from EUPIA GMP guideline

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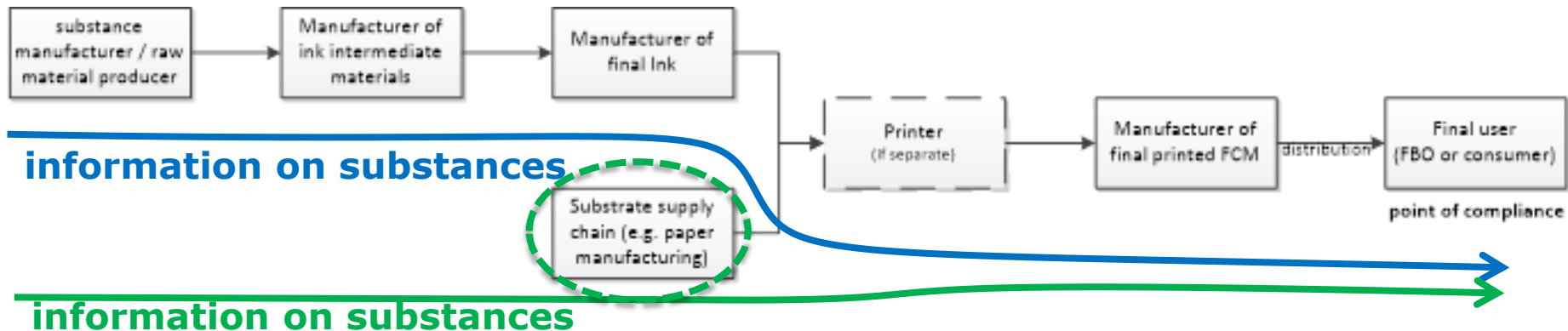
Printed FCMs

Problems of regulating p-FCMs

- **Point of compliance**
 - Food Business Operators, particularly small FBOs
- **Complex supply chain**
 - Communication is important!
- **Number of substances**
- **Combination with other materials**
 - Paper and board in particular
 - Absence of functional barriers
- **Missing rules for verification of compliance**
 - Equivalent to Article 17, 18, Annex III and V of R 10/2011
 - No known analytical methods – CoE to start on inventory
 - Technically challenging
- **Need to ensure comprehensive and transparent risk assessment!**

Printed FCMs

Complex supply chain



- **Final FCM must be safe and comply – legal certainty needs to be ensured**
 - Substances from printing inks
 - Substances from substrate e.g. paper and board, plastic, adhesives, coatings
- **Paper and board particularly complex**
- **Communication throughout supply chain needs to be ensured**
 - Composition
 - Conditions of use
- **Compliance complicated by**
 - Confidential information, liability disclaimers, legal issues
 - Lacking standards and sheer complexity
 - Methods for combined materials
 - Conditions of use

Printed FCMs

Very large number of substances

- **How many are there for printing inks?**
 - Germany list >700 substances
 - Switzerland has inventory of ~5000 substances
 - 10 ppb limit, NIAS...
- **Positive authorised list of suitable substances**
 - Important tool under Regulation 1935/2004
 - Mandatory for EFSA evaluation once list is established
 - Historical rate for plastic substances is 25 per year
 - Significant allocation of resources, long term management
- **Efficiency of this approach?**
 - Evaluation of substances for manufacturing
 - Compliance of final material

Printed FCMs

Comprehensive and transparent risk assessment

- **Role of EFSA**
 - Evaluate substances for positive authorised list
 - Must be consulted before adoption of EU measures
 - Process needs to be transparent
- **Role of industry**
 - Currently under Article 3 to demonstrate compliance or national legislation
 - Regulation 2023/2006 for GMP and avoid offset
 - Approach for NIAS etc under Article 19 of Reg 10/2011
- **Role of Member States**
 - Currently enforce Article 3 or national legislation and Reg 2023/2006
- **Need to ensure transparency for safety and enforceability**

The traditional approach

Scope + definitions

Rules on composition

- **general rules**

- **positive list**

several decades work

- **(list of) limits**

procedure not clear, significant work

- **specific provisions on materials**

Rules on documentation

- **declaration of Compliance**

significant work

- **supporting documentation**

problems hard to resolve

Rules on verification of compliance

resources not available

Printed FCMs

What are the needs?

- **Improved responsibility for business operators**
 - Focus on risk of final materials
 - move away from focus just on 'compliance'
- **Improved flow of information**
 - Information exchange in the supply chain
 - Information exchange with competent authorities
- **Equal treatment EU business operators and importers**
- **Lower burden to CA, higher level of compliance**
 - Independent verification
 - Enforcement is practicable and not just theoretical
- **Realistic burden to risk assessors**
 - Assessing 5000 substances in reasonable timeframe not realistic
 - Public Authorities cannot take responsibility for materials they cannot fully understand
 - RA to define approach rather than do the work
 - Specific RA limited to special cases but still available

Typical rules in legislation for risk assessment

Generic rules on assessment of substances

- **Example:**
 - CMR substances not permitted
 - if not CMR → 10 ppb limit
 - if no structural alerts, basic toxicology established → 50ppb
 - higher migration? EFSA evaluation!
- **possibly different rules for different contact (inside, outside, gas-phase, off-set)**
- **established on basis of EFSA opinion**

Database of assessed substances

- **to avoid duplication + sharing of burden**
- **mainly migration limits**

Printed FCMs

Next steps

- **Roadmap**
 - Four-week feedback mechanism
 - All stakeholders invited to respond
- **Commission study to support the work**
 - Foreseen end 2017 – beginning 2018
- **Draft measure**
 - In discussion with stakeholders