Regulating Printed Food Contact Materials

- Problem definition
- Elements for legislation
- Way forward

5 May 2017

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
OVERVIEW

State of play

The problem of regulating printed FCM

Two models

- The traditional approach (Plastics Regulation)
- Designated bodies

Initial scope

Way forward

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
State of Play

Summer 2016 German notification on printed-FCM
• Commitment confirmed in autumn

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

Ready by mid 2018

Rationale
• Health concerns – German notification + JRC study
• EU measure more effective in protecting health
Scope of the p-FCM project

Objective:
- to protect against constituents of printing inks

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, colorants
- processing aids for printing (e.g. mineral oil)
## Printed FCM

### What is migration?

<table>
<thead>
<tr>
<th></th>
<th>Migration Type</th>
<th>Description</th>
<th>Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Direct Migration</td>
<td>Direct migration from print to the food, in situations where the food is in direct contact with the print</td>
<td><img src="inksubstrate_direct_migration.png" alt="Diagram" /></td>
</tr>
<tr>
<td>2</td>
<td>Through Migration</td>
<td>Penetration through the substrate to the reverse side of the print</td>
<td><img src="inksubstrate_through_migration.png" alt="Diagram" /></td>
</tr>
<tr>
<td>3</td>
<td>Set-off Migration</td>
<td>Set-off from the print to the reverse side while being stored in a pile or reel</td>
<td><img src="inksubstrate_set-off_migration.png" alt="Diagram" /></td>
</tr>
<tr>
<td>4</td>
<td>Gas Phase Migration</td>
<td>Volatilisation and condensation of components after heating</td>
<td><img src="inksubstrate_gas_phase_migration.png" alt="Diagram" /></td>
</tr>
</tbody>
</table>

### Example from EUPIA GMP guideline

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
The problem of regulating p-FCM

Point of Compliance:
- (small) Food Business Operators

Complex supply chain
- communication

Number of substances

Combination with other materials
- (recycled) paper and board

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

Ensure transparent risk assessment
I: Compliance at the FBO

Example: A small bakery

- the baker prints logos on bags and other paper FCM
- the baker *designs* the bags, and has them printed
- printing ink on outside and possibly inside of packaging

The bakery is the point of compliance

- usage conditions known: food, time, temperature
- competent Authorities may control the bakery

How should a baker comply to a Regulation on printing inks?
II: Complex supply chain

Final FCM needs to comply
- legal certainty must be ensured

Throughout supply chain communication on
- composition
- conditions of use

Complicated by
- confidential information, liability disclaimers
- lacking standards and sheer complexity

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in any way propose or reflect final legislation.
III: very large Number of Substances

Positive listing of suitable substances:
- important tool under Regulation 1935/2004

How many?
- Germany list >700 substances
- Switzerland has inventory of ~5000 substances
- 10 ppb limit, NIAS, ...

Mandatory procedure for positive listing
- Regulation 1935/2004: EFSA shall evaluate each substance
- historical rate plastics is 25/yr
- significant allocation of resources, long term management

Efficiency in doubt
- Evaluation of substances for manufacturing
- Compliance in final material

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
IV: presence of substrate

Substances in Final FCM from
- printing inks
- substrate(s): plastic, paper + board, adhesives + coatings

Paper and board particularly complex
- natural material
- printing inks present after recycling

Compliance problems further complicated
- methods for combined materials
- further liability and legal certainty issues
V: Missing rules for verification of compliance

Article 17, 18, Annex III, V of Regulation 10/2011
- complex guidance

Common rules necessary for legal certainty
- certainty for industry, as well as competent authorities

Not easy to create
- 30 year unfinished project for plastics
- missing analytical methods (10 ppb limit for many substances)
- existing rules and guidance help to an extent
- migration modelling, partial overlap with plastics?
- CoE work?

Documentary evidence also important for verification
- migration modelling
VI: Transparency of risk assessment

EFSA evaluates substances
- Generally very transparent

FCM manufacturers have a big role in risk assessment
- generally under Article 3
- under R 10/2011 everything under Article 19, e.g. NIAS

- ensuring that the final material is safe
  (modelling, conditions of use, foreseeable use, ...)

in printed FCM this transparency needs to be ensured
- enforceability and safety
The problem of regulating p-FCM

Clarifications?

Discussion?

Coffee?
Solutions to Regulating p-FCM

2 serious options
  • several option have been considered internally

Traditional structure of Regulation 10/2011
  • presently considered problematic

New Approach based on designated bodies
  • selected for further development
Solution I, the traditional model

Scope + definitions

Rules on composition
- general rules
- positive list
- (list of) limits
- specific provisions on materials

Rules on documentation
- declaration of Compliance
- supporting documentation

Rules on verification of compliance

---

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Solution II: using designated bodies

Essentially a new approach to compliance

Shift in responsibilities to designated bodies

Rule base directing the work
  - legislation, standards, guidance, internal rules

Central database
  - to facilitate exchange of information in supply chain
  - accessible by public authorities

Governance committee
  - Commission, Member States, Designated bodies, Stakeholders

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in any way propose or reflect final legislation.
Designated body: compliance work

- Final FCM
- Rule Base
- Assessment of final FCM by designated body
- Documentation in Database
- Compliance certificate

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Designated body

*Designated by Member States after accreditation*
  - Commercial laboratories
  - Other consultants

*Independent from FCM manufactures*
  - impartiality and confidentiality

*Responsible for certifying compliance work*
  - at each stage of manufacturing
  - they can also carry out the compliance work
  - possibly some self-certification (FBO’s, retail, distribution)

*Certification is the only added burden*
  - the other work should be carried out already

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Intermediate material II

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.

Compliance certificate intermediate C

Documentation in Database intermediate C

intermediate FCM made out of C and D

Assessment of intermediate FCM by designated body

Compliance certificate intermediate D

Documentation in Database intermediate D

Rule Base

Compliance certificate
This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Activities of a designated body

Identification of (migrating) substances

Migration testing

Toxicology
  • Testing (where not available)
  • Interpretation (partially a new regulated activity)

Evaluation of applicable rules

Decision on safety
  • (partially a new regulated activity)

Certification, documentation, control parameters

Actual activities subject to point in supply chain
Rule Base

Legislation sets out main obligations
- procedures, functioning of the system
- hazard/exposure based rules, e.g. CMR, nano, ...
- rules concerning risk assessment
- rules based on contact mode

Standards
- technical + analytical procedures

Guidance
- where rules are available, but too much technical detail for legislation, flexibility is needed, or change expected

Internal rules made by designated bodies
- only if no other rules apply to a specific case
- can be ad-hoc
- mandatory documentation of rules/reasoning
- possibly notification to EFSA
Evaluation of toxicology/suitability

Evaluation by designated bodies: conservative
- Low exposure
- Well established toxicological tests
- Criteria in general rules on basis of EFSA opinion
- Further guidance to be established for this purpose

If substance fails to meet conservative criteria
- E.g. in case of higher exposure or a specific concern
- EFSA evaluation → authorisation → positive listing

Conservativeness needs to strike a balance
- EFSA evaluation capacity is limited
- The system thus facilitates prioritisation
Access to information

*Dossier information stored in central database*

**Competent authorities + EFSA: access to all information**
- dossiers + internal rules used by designated bodies

**Designated bodies can access *relevant* dossiers**
- info on the intermediates stored by designated bodies

**FCM manufacturers + FBOs can access basic info**
- parameters for control and identification
- not to detailed, confidential, info on composition

*(Optional public access to selected information)*
- e.g. basic information on the materials, producers, designated bodies
- e.g. other information designated by manufactures
- risk however that it is misleading, because partial
Control of the system by CA’s

Accreditation and Designation
- To ensure sufficient quality of the bodies

Control of assessment dossiers
- To verify adequateness of the work of the bodies
- To verify whether it is in compliance with rule base
- To monitor reasoning on risk (internal rules)
- To understand control parameters
- CA can overrule DB's

Market controls on basis of control parameters
- i.e. traditional FCM controls according to OFFC
- control parameters in compliance certificate
- defined by designated body as part of certification
- parameters to identify a material as the certified material
- relevant quality parameters, e.g. SMLs

Control of dossiers and OFFC controls on risk basis
- not all dossiers/material

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Governance

Governance Committee
- expert group similar to this group
- established by the Regulation
- Member States, EFSA
- representation of designated bodies, industry, FBO’s

Tasks
- determine where further/formal rules are needed
- discuss specific dossiers

Typical agenda
- prioritisation of new cases → public list of issues
- management of technical task forces
- discussion of on-going cases
- preparation of new rules
This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in anyway propose or reflect final legislation.
Key changes with respect to traditional approach

Rules for supporting documentation formalised
- Use of central database to facilitate access

Risk assessment further formalised
- not left to business operators, but to designated bodies

No detailed compliance rules
- designated body's certification means it is compliant

Positive listing only in case of problematic use
- prioritisation of evaluation

Formal role for governance committee
- detailed risk management & procedural matters
Expected Shifts in burden

**Official controls**
- Lower burden per control, better documentation, more to the point
- Imports follow the same rules

**Central Authorities**
- New burden, designation of bodies and checking of their work

**FCM manufacturers**
- Obligatory use of designated bodies
- More tailored rules, shorter time to market

**FBO**
- Improved information
**long term benefits**

*Formalised approach to assessment and documentation*
- increased transparency & better access
- more efficient use of (scientific) resources

*Detailed technical/scientific work decentralised*
- Authorities focus at norm-setting

*Prioritization of EFSA risk assessments*
- risk assessments become exception → only those cases that really require it

*Flexibility and speed for businesses*
- clarity in the supply chain

*Same approach perhaps also for other FCM*
- now only printed FCM

---

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion on potential new legislation, but does not in any way propose or reflect final legislation.
Possible drafting complications

**Legal basis**
- role of EFSA and official controls

**Need to**
- establish a database
- designate bodies

**Establish general rules**

**Legal certainty on certification**
- competent authorities may not accept
Way forward

**Hiring of contractor to**
- identify labs/consultants that could act as designated bodies
- establish main procedures
- establish database architecture

**Decision to take new approach or fall back on traditional approach**

**Drafting of Regulation**

**Transition period following adoption**
- Designate bodies
- Establish database
Conclusion

*Drafting difficulties for p-FCM*
- complex technical rules on verification of compliance
- solution for information exchange in supply chain

*Two potential approaches*
- Traditional: does not solve drafting problems
- Designated bodies: does solve these problems

*Commission not yet committed to any approach*
- we raised your awareness on potential new approach