WG food contact materials

Monday 30 January 2017

European Commission
DG SANTE, Unit E2 – Food Processing Technologies and Novel Foods
Food Contact Materials

This presentation does not necessarily represent the official views of the Commission
Agenda

(Draft 8th amendment to Plastics Regulation)

‘Short’ Discussion on major work items for 2017
- Evaluation of FCM
- Information in the Supply Chain
- Union Measure on printed FCM

Authorisation of recycling processes
- Text of the Decisions
- Guidelines

Any other business
- Mineral oils monitoring
- ‘LiquidSeal’
- Information from Belgium on BPA and BPS
- Polymeric absorbers used on honey
- SANTE.F fact finding mission
- Ceramics
8th Amendment

Not on agenda, internal draft not ready

Procedure
- Feedback mechanism applies
  (=1 month public consultation)
- written consultation MS-experts (you) mid-February
- possible information point in tox-SC of 27 March
- actual vote probably end of April

concerns only 4 substances (so-far)
EVALUATION
Evaluation of FCM

- Backwards looking at 40 years of FCM legislation
- How well does the present legislation function?
- Focus on framework, but includes all legislation in force, including recycling and A&I
- Output: staff working document

printed FCM

- Forward looking
- Output: New Regulation

Studies on compliance info in the supply chain

- Backward and Forward looking
- Feeds partially into the other two activities
- is also part of the other two activities
- Output: staff working document on DoC and SD
FCM Evaluation

Ex-post evaluation

- FCM legislation is 40 years (Directive 76/893/EEC)
- Is it effective, efficient and sustainable?
- Focus at level of Framework Regulation

Objectives:

- To understand whether EU procedures are adequate
- To prepare possible further harmonisation

Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice, so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

- endanger human health,
- bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Article 3

The Council shall, under the procedure provided for in Article 100 of the Treaty, adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives).

Such specific Directives may include:

(a) if possible and if necessary, a list of the substances the use of which is authorized to the exclusion of all others;
(b) purity standards for such substances;
(c) special conditions of use for these substances and/or the materials and articles in which they are
Why evaluate?

40 years old legislation, never evaluated

Doubts on correct functioning

- Non-harmonised
- Risk Assessment
- Information exchange in supply chain
- Difficulties with implementation and drafting of new legislation → e.g. how to risk assess 8000 substances

Very little concrete evidence

- JRC study provides clear evidence on non-harmonised
- Otherwise it is difficult to substantiate perceived problems
Approach

Ex-post evaluation of FCM legislation
• responsibility at level of DG SANTE

potentially employ contractor(s) for detailed work
• two studies
• subjects: p-FCM, 40 years of FCM

FCM Conference
• preferably before summer

Thereafter
• regular evaluation study on FCM + study on p-FCM

Still under preparation, so change is possible
Evaluations

Tool defined under better Regulation framework


Evaluation is defined as:

evidence-based judgement whether an intervention has:

- been effective and efficient,
- been relevant given the needs and its objectives,
- been coherent both internally and with other EU policy interventions and
- achieved EU added-value.

Intervention logic

- Needs → Objectives → Inputs → Activities → Outputs → Results
Discussion on possible research questions/topics

• to ensure contractor can concentrate on finding evidence, rather than to provide us with further questions

your views are important

• draft questions for discussion
• to help us build intervention logic
• to help us set priorities

➔ effective drafting of tasks for contractor

FCM is complex

➔ First, less general, more concrete questions
Possible Questions

SEE INDUSTRY PRESENTATION
Remember 1

- These questions are to build intervention logic
- to define concept such as objectives and results
- to determine effectiveness, efficiency, relevance, added-value

Remember 2

- not the intention to criticise present framework
- first gather evidence
- Result: identification of necessary follow-up activities, if any
Discussion

Any Feedback, Questions?

Alternatively:

• SANTE-FCM-Consultations@ec.Europa.eu
Use of compliance information in the supply chain

STUDY
Study: information transfer in supply chain

Does this mechanism function?

- Declarations of Compliance + Supporting documentation
- our feeling is that the functioning of this mechanism could be improved
- efficiency of restrictions; safety of plastic materials
- REFIT platform recommendation on Declarations of Compliance

Why?

- to understand the functioning of the plastics Regulation
- to inform future harmonised measures
Two Objectives

**backward focus**
- how does it function now?
- feeds into plastics Regulation + Evaluation

**forward focus**
- DoC for all FCM (REFIT platform)
- plastics Regulation
- printed FCM

*Carried out by Commission Staff*
- eventually merged with other projects
Present Survey is starting point to identify priorities

• to increase our understanding

Please participate, this afternoon:

• 27 responses from MS (but some MS submitted several)
• 98 responses from Industry
• 18 from associations, including ‘many’ national associations

The survey is on-line:

• [http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/non_harmonised_en](http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/non_harmonised_en)
• bottom of page!
• DL: 10 February
A new harmonised measure

PRINTED FCM
New harmonised measure on printed FCM by mid 2018

Prioritisation – health concerns
- German notification, scientific study (napkins)
- adoption foreseen mid 2018

Initial Scope
- printed food contact materials
  = printing inks + food contact materials that are printed

Simplification
- information in the supply chain and compliance
- possibly over 5000 substances involved

Presently under preparation internally
Paper and Board is main printed FCM

More complex than plastics?
- Lacks the barrier properties of plastic
- Lacks well defined testing approach

P&B has high recycling rate
- Compliance issue because of existing PI
- Costs associated with grades and barrier materials

Hence, P&B cannot be ignored when considering PI
- The measure will be on Printed FCM (P-FCM)
- For plastic the situation is simpler, but not fundamentally different
P-FCM approach

Harmonise the German text?
- positive list?
- methods and rules for verification of compliance?
- rules on materials

A simplified approach?
- list with limits – we do not care where a substance originates
- methods and rules for verification of compliance?

An integrative approach?
- other existing legislation
- industry guidelines

Fundamentally different approach
- Re-definition of roles for business operators and authorities

Avoid long/complex transitional approaches
**Approach**

*Legislation that works in practice*
- effectiveness and efficiency, enforceability, compliance

**Phase 1: Identify main elements for legislation**
- starting point: notified German draft (+ industry guidance)
- analysis of what is required for achieving compliance
- elements (or options) for legislation

**Phase 2: Put the elements together**
- focus on practical aspects of the functioning
- i.e. identify and resolve problems
- done by contractor

**Phase 3: Drafting of final text**
2017

**Now-June**
- Recycling Decisions
- Hiring of contractor(s)
- Identification of main elements for p-FCM legislation

**June-October**
- Conference on FCM
- Testing p-FCM of legislation
- Evaluation

**October-December**
- Drafting of p-FCM Regulation
- Evaluation

*This timing is indicative and may be subject to change*
120 Decisions on

RECYCLING
Why Regulate recycled plastics?

"virgin" Plastic

Plastic compliant with Reg. 10/2011

Recycling

⇒ plastic packaging waste residues/contaminants
   - previous use (e.g. food, shampoo)
   - "misuse" (e.g. paint, detergents)
   - non-food use material (non-authorised substances)
**Plastic**

- Regulation (EU) No 10/2011
- Specifies the permitted composition of the plastic
- When placed on the market migrants are known, risk assessed and controlled
- During control, the migration limits and documentation are verified

**Recycled Plastic**

- Regulation (EC) No 282/2008
- During use plastic can be contaminated with unknown contaminants
- Only a recycling process that sufficiently decontaminates is permitted
- Control: is the process as authorised, and is it operated accordingly?
- No laboratory control is possible
Recycling Process

Restrictions on Input, Process, output:
- Input: source of the plastic, washing, shape (d)
- Process: unit operations, critical steps, parameters (e)
- Output: max percentage, conditions of use (f, g)

In addition prescriptions on monitoring (h)

(letter refer to Article 6(3) of Regulation (EC) No 282/2008)
State of Play

EFSA has published the Opinions

• Initial authorisation phase completed in 2015
• Evaluations are on-going, new processes

Authorisations are delayed for several reasons

• Drafting process is now finally advancing

Three main activities:

• Drafting of 120 individual Decisions
• Resolution of certain problems
• Drafting of Guidance and CMSS format
Decisions

*Individual Authorisation Decisions For each process*

*Enacting terms: essentially administrative*

- **Recitals**
  - States that the process is authorised provided conditions in Annex are met
- **Adressed to the applicant**

*Annex:*

- **Process description**
- **Specifications and restrictions**
Decisions

**Basis provided by Article 6:**

1. **Decision addressed to applicant**
   - granting or refusing authorisation

2. **Account of the opinion of the Authority + other legitimate factors**

3. **Decision granting the authorisation shall include:**
   - (a) the name of the recycling process;
   - (b) the name and address of the authorisation holder(s);
   - (c) a short description of the recycling process;
   - (d) any conditions or restrictions concerning the plastic input;
   - (e) any characterisation of the recycled plastic;
   - (f) any conditions or restrictions concerning the recycling process;
   - (g) any conditions in the field of application of the recycled plastic that has been manufactured by the recycling process;
   - (h) any requirements concerning monitoring of the compliance of the recycling process with the conditions of the authorisation;
   - (i) the date from which the authorisation is effective.

4. **Decision valid in the Union after publication in OJ**

   (Article 6(3) info also visible in separate public register)
Controlling the process

**Goal:** recycled plastic safe for human health
- cleaning efficiency is met

**Achieving compliant operation**
- the technology is as in the application
- it is operated in accordance with the authorization
- i.e. parameters of critical process steps are respected
- monitoring

**Auditing – verifying compliance**
- controlling whether the technology complies
- controlling whether each batch is compliant

**Documentation – being able to audit**
- description of process
- traceability of batches
- based on monitoring
Single focal in GMP documentation
- defines technology
- translates authorisation to practice
- facilitates audits
- provides entry into application documents

It should be 2-4 pages:
- identification of technology
- brief policy statement on safe operation
- definition of control variables and validation rules

Mandatory document:
- template defined in Regulation
- business operator must fill it out on the basis of application documents
Full Dossier

EFSA Opinion

Critical Parameters

Authorisation Decision

Compliance Monitoring Summary Sheet

Data Records Indicating batch compliance

Internal Documents (Manuals, GMP)
On-going work

Presently: Drafting of Decisions
- Quick advancements over next 3 months

Resolution of problems
- Determination of level of contamination based on almost 20 year old study. Representative for internal market? Representative for international trade?
- HDPE/Polyolefin recycling
  → potential requirement for analytical work by recyclers

Finalisation of
- CMSS template definition
- Guidance
Solve open questions with a monitoring requirement?

- The 5% non-food consumer products limit
- Imports and production out-side of the EU
- The present contamination level
- Other issues, such as actual decontamination, systemic contamination sources...

HDPE authorisation
Mineral oils monitoring
‘LiquidSeal’
Information from Belgium on BPA and BPS
FVO fact finding mission
Polymeric absorbers used on honey

AOB
Mineral Oils

Recommendation has been published

JRC will organise drafting of guidelines

- Harmonised approach
- To provide help to those MS that do not have the capability yet
- Your participation is important: the need for guidance is driven by your needs

Please watch communications from the JRC
LiquidSeal: innovative coating put on fresh fruit

Food contact or food additive?

**In General:**
- If intended or foreseeably consumed with the fruit it falls under food additives legislation, not an FCM
- If intended to be removed it is an FCM. Labelling may be needed to indicate the consumer should remove it.
Information from Belgium on BPA and BPS
Directorate F (former FVO)  
Fact-finding missions 2017

• Romania, Hungary, Germany, the Netherlands

• Objectives:
  ➢ Collect and analyse information on the general situation, regulatory measures applied and main characteristics of MSs' official controls
  ➢ Investigate impact of current EU and national legislation on functioning of internal market

• Feed into planned evaluation on FCMs