WG food contact materials

Monday 30 January

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

This presentation does not present any official views of the European Commission

Agenda

Authorisation of recycling processes

'Short' Discussion on major work items for 2017

- **Evaluation of FCM**
- **Information in the Supply Chain**
- **Union Measure on printed FCM**

Any other business

- **Questionnaire on risk assessment**
- **Status of migration testing guidelines**
- **OML dry-foods under 10/2011**

European Commission

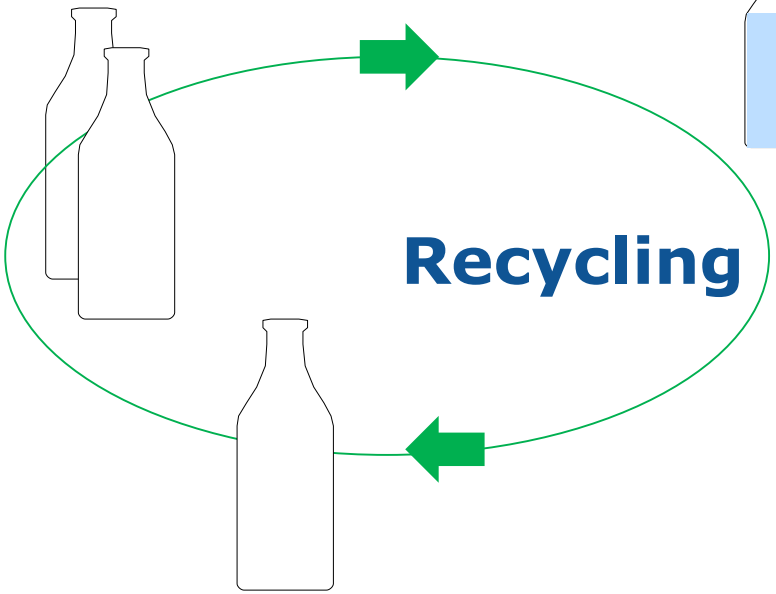
120 Decisions on

RECYCLING

Why Regulate recycled plastics?

"virgin" Plastic

Plastic compliant with Reg. 10/2011



⇨plastic packaging waste

residues/contaminants

- previous use

  (e.g. food, shampoo)

- "misuse" (e.g. paint, detergents)

- non-food use material

  (non-authorised substances)

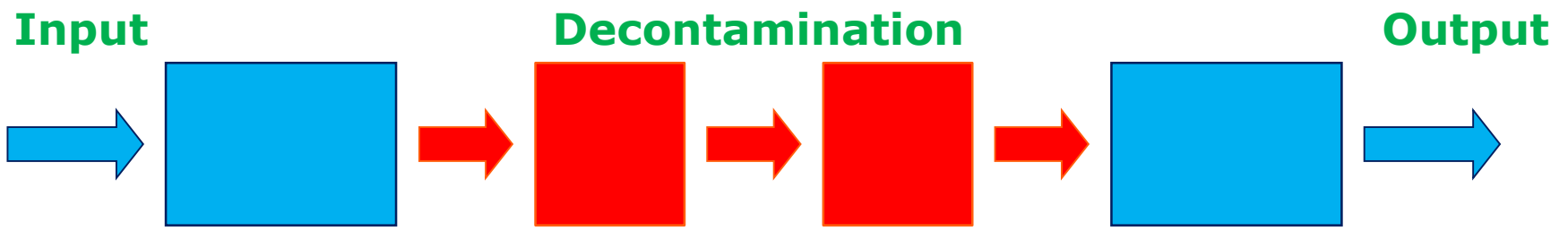
Plastic

- **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)

(letters 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**
- **Addressed to the applicant**

Annex:

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

Decisions

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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;
   (f) any characterisation of the recycled plastic;
   (e) 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

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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**

Compliance Monitoring Summary Sheet

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Single focal in GMP documentation

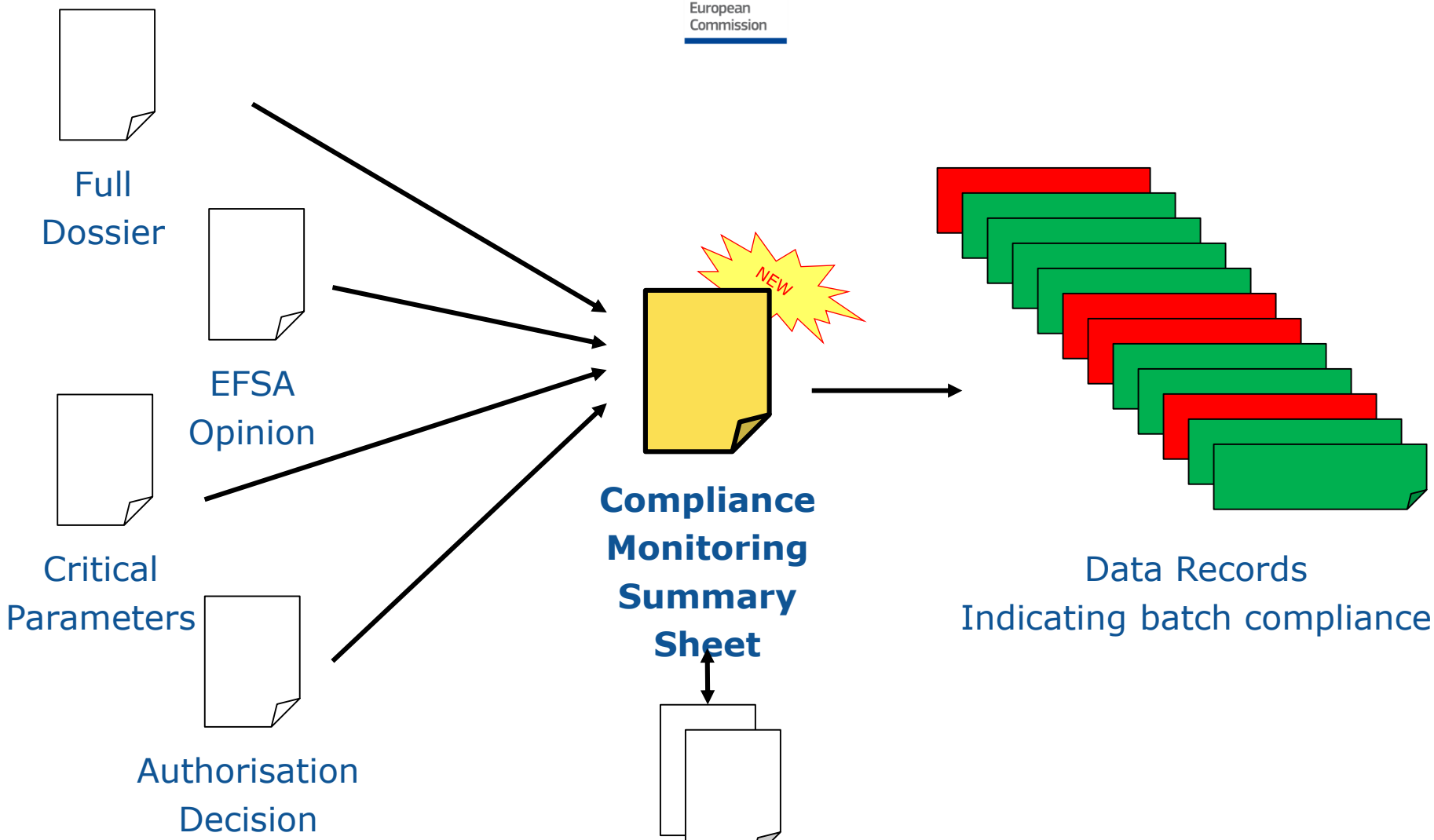
- **defines technology**
- **translates authorisation to practice**
- **facilitates audits**
- **provides entry into application documents**

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
NEW
Compliance
Monitoring
Summary
Sheet
Internal Documents
(Manuals, GMP)
Data Records
Indicating batch compliance

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**

EVALUATION

perspective

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

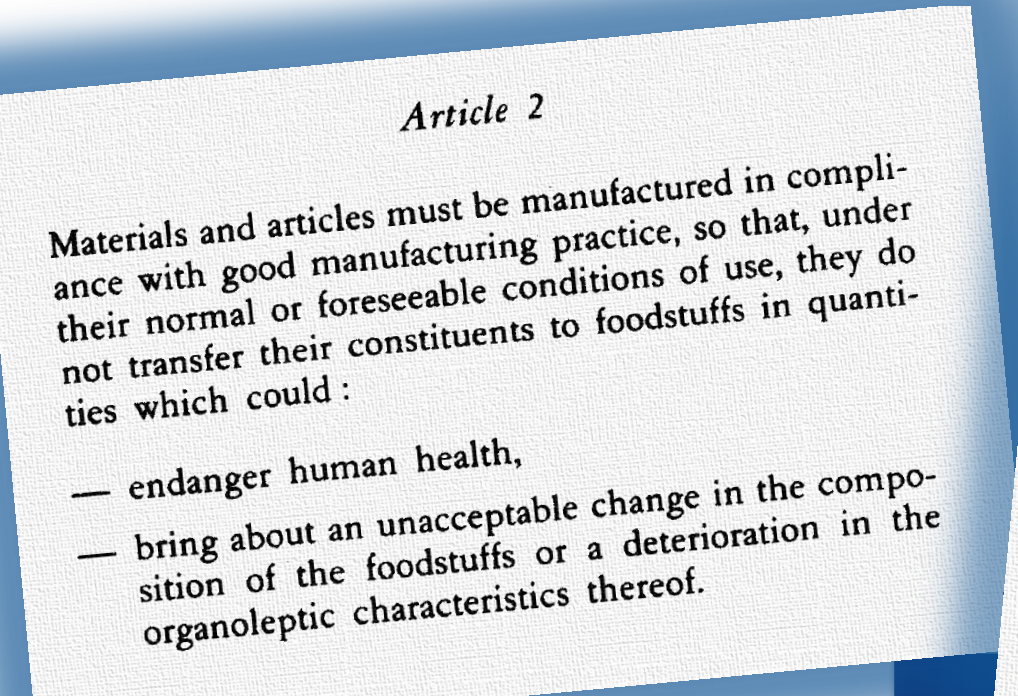
European Commission

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**

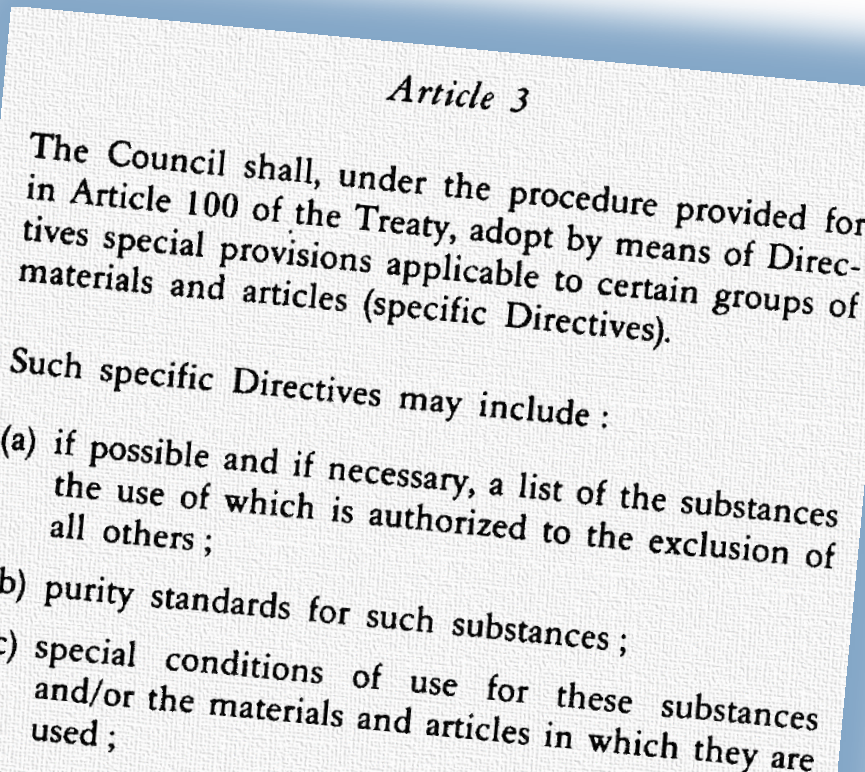


Article 2

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 used ;

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

- **http://ec.europa.eu/smart-regulation/guidelines/ug_chap6_en.htm**

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**

Questions

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

Q1: Focus on Risk Management

- **What is the intervention logic? How do we ensure acceptable risk from FCM?**
- **Who does risk assessment/management?**

  Commission, EFSA, MS, business operators?
- **Is the outcome true in theory and in practice?**

  Intended vs. foreseeable vs. actual use, monitoring, enforcement
- **Are there gaps in the risk assessment?**

  Starting/Final materials, NIAS, non-harmonised
- **What is the scope of 'compliance-work'?**

  RA role of business operators
- **What is the burden of risk assessment?**

  EFSA capacity, lab animals, time to market,
- **Is the essentially deterministic approach appropriate for meeting Article 3?**

  FCM is either safe of not safe, no probability, uncertainty, simplified exposure assumptions, inherent safety…

Possible Questions

Q2: Is it appropriate to distinguish specific materials?

- **Why do we make a difference between materials?**

  Historical reasons? Efficiency? Different approach needed for RA or RM?

- **Is the list actually complete?**

  Stoneware?

- **What about combinations such as composites?**

  Solve the matter by not applying limits?

- **Is it possible to distinguish between materials?**

  e.g. Rubbers vs. Plastic FCM

Possible Questions

Q3: Are the tools Article 5 provide us with appropriate and sufficient?

- **Should positive lists be the main tool?**
- **Practical aspects**

  e.g. Enforceability
- **What different approaches are used under other similar legislation?**

  e.g. REACH, food safety, product safety, occupational safety? National FCM legislation?

Possible Questions

Q4: Are the procedures under the Framework adequate?

- **Article 8-12 on authorisations?**
  - EFSA guidelines
  - Submission of applications via MS
  - Removal of authorisation
  - New Scientific information
- **National/EU responsibilities?**
- **Confidential information?**

Possible Questions

Q5: Enforcement

- **What is being enforced?**

  which measures, which aspects of those measures, which substances imports, market controls

- **What are the responsibilities and activities of the stakeholders?**

  Competent Authorities & Business operators

- **What information is available?**

  DoC, SD, analytical testing, …

- **What options exist for enforcement?**

Possible Questions

Q6: (Internal) Market (see JRC study)

- **How does the market work?**

  Manufacturing chains, internal circulation, size
- **Differences in legislation?**

  EU, National, International
- **Are differences in company size relevant?**

  Micro businesses, SME's, larger enterprises
  Innovation, time-to-market
- **What information is available?**

  DoC, SD, analytical testing, …
- **What options exist for enforcement?**

(Q7: Questions on the implementation of specific measures)

Discussion

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**
- **<u>first</u> 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**

Survey

Present Survey is starting point to identify priorities

- **to increase our understanding**

Please participate, this morning:

- **25 responses from MS**
- **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**
- **bottom of page!**
- **DL: 10 February**

European Commission

A new harmonised measure

PRINTED FCM

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

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

- **For plastic the situation is simpler, but not fundamentally different**

The measure on printed FCM will however not lead to compositional rules for P&B

- **e.g. it will not set out a Union list for substances that can be used to manufacture P&B**
- **only rules that would be relevant for dealing with the printed layer, if any, may result**

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

Final approach to be determined!

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**
- **potentially 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 subject to change