



Meeting with FCM European Professional Associations

6 September 2019
Recycling + Glymo + Phthalates

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1

Topics 6 September

14th Amendment
Recycling
Glymo
Phthalates
AoB



2

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RECYCLING

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State of Play

Regulation (EC) 282/2008 requires

- **Commission to take decisions on individual authorisations**
- **thereafter only recycled plastic with authorised process may be on market**
- **we could not authorise appropriately;**
clarification of transition and obligations in Regulation required

→ Amendment of R 282/2008 under preparation

Next steps (during next few weeks):

- **consultation MS, EFSA, and Industry**
- **consultation Commission services**

4

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A: Transition after adoption of authorisation Decisions

without amendment some plastic would become illegal overnight

Three distinct cases

- 1. PET processes that did never apply**
- 2. PET processes that were modified**
(not theoretical as shown by ongoing applications concerning such modifications)
- 3. Many other plastic materials**
(affects many polyolefins such as HDPE, and chemical recycling)

5

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B: Clarification of Obligations needed

General obligations for the operation of recycling processes

The different role between authorisation holders and recyclers

Administrative practices for authorisation holders

Putting in place the Compliance Monitoring Summary Sheet

Enforcement and compliance

6

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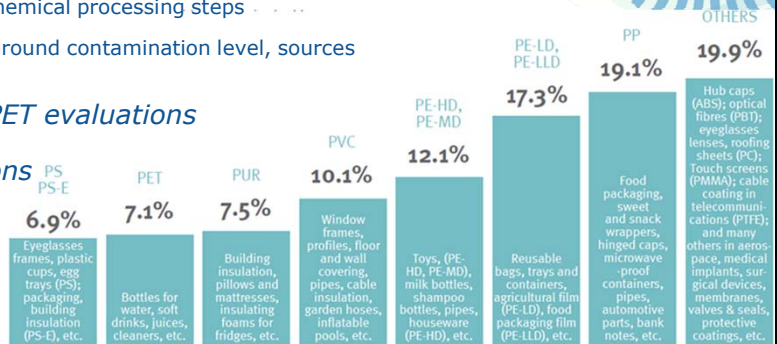
Considerations Non-PET materials

Different approach probably needed for these materials

- increasing importance under circular economy
- increasing innovation;
 - new processes differ from mechanical recycling with a decontamination step
- **no explicit scientific evaluation approach as for PET**
- **legislation does not require challenge test;**
 - 'other appropriate scientific evidence' also accepted
- Differences in collection and sorting + chemical processing steps
- **key data may be different**, e.g. background contamination level, sources

time pressure because of efficient PET evaluations

→ need to avoid inconclusive opinions



7

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New processes

Other plastics, other processes?

- do these need to decontaminate? Source?
- how well do these decontaminate?
- is their output compatible with 10/2011?

Chemical recycling presently out of scope

- 'the next big thing'- says chemical industry
- R282 assumption was, mostly, feedstock recycling
- safe because of pyrolysis step

Innovations + absence of definition → grey zone

- several kinds of processes that could be 'chemical recycling'

→ Chemical recycling likely needs including in scope to avoid transition issues

grey zone

Just Sorting

...

Mechanical Recycling

...

Super Critical Extraction

...

Dissolution

...

Hydrolysis

...

Feed Stock Recycling

8

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Scientific basis for Evaluations



EFSA Journal 2011;9(7):2184

SCIENTIFIC OPINION

Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food¹

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)^{1,3}
European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of EFSA deals with the criteria to be used for safety evaluation of a recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. The principle of the evaluation is to apply the cleaning efficiency of a recycling technology or process.

New processes

- Different materials
- Different contaminant levels
- Different sorting principles
- Different cleaning principles
- Challenge test potentially not appropriate

Do we need other criteria?

Do we need a procedure?

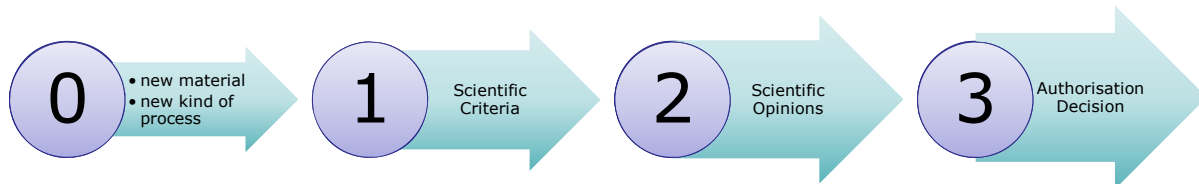
Requires answering by EFSA and by Industry

9

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Potential two step scientific approach for Non-PET



Consortium(?) would apply to establish scientific evaluation criteria for a new type of recycling process

- 1. EFSA establishes scientific evaluation criteria (as done for PET in 2011)**

Individual applicants apply for authorisation based on established criteria

- 2. EFSA publishes opinion on the safety of the process**

Procedure to ensure legal certainty

- **but there could be other ways than this**

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Consultations

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Three main elements

(on which we will consult in three separate texts)

A: Transition approach

- **mechanical PET now, the rest later (including closed loop and HDPE)**

B: Clarification of obligations

- **Obligations for Authorisation Holders + Recyclers**
- **Obligations for competent authorities**
- **meant to Simplify the Authorisation Decisions**

C: new rules for all other plastics (at a later stage)

- **All recycled FCM plastics to be in scope**
- **Some can be used without authorisation**
- **Procedure for EFSA to establish evaluation approach (2-step)**
- **only later (requires new Regulation)**

12

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Over-all foreseen Timeline

Step 1: First two sets of amendments (transition + obligation)

- **external and internal consultations**
- **aim is adoption in Q2 2020**

Step 2: Adoption of individual Authorisation Decisions

- **preparation + consultation during scrutiny period**
- **aim: adoption in Q3 2020**

Step 3: Notification and Publication of register

- **publication of register is T=0 for provisions on transition**

Step 4: Establishment of CMSS

- **which will involve MS competent Authority + Business operators**

Step 5: Other plastics

13

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A: Transition

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Possible PET Transition procedure

1. Time=0: Union Register of authorised processes
2. unauthorised PET may remain for 6 months
3. thereafter, only PET manufactured with an authorised process may remain
AND
other PET, but conditional to an on-going EFSA evaluation
4. EFSA evaluates (6+6 months + stop-the-clock)
5. a Decision accepting or rejecting Authorisation is presented for vote
6. only Authorised PET on the market after Time= 6+12+~6+6 months

Note:

- this assumes mechanical PET recycling

→ after about 2,5 years following adoption of initial Decisions no more unauthorised PET

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Foreseen Transition PET Processes

Entry into force: Article 16 is amended

- **Commission to establish Union Register just after notification of Decisions to applicants**
- **From that moment only plastic with authorised and suitable process**
- **Article 3 + 3a** (only plastic with an authorised suitable process), **Article 9, 10** (enforcement), **and 12** (DoC) **apply from publication of Union Register**

Authorisation: Article 13 is replaced in its entirety by the following

- **Commission to submit all opinions to standing committee**
- **after entry into force of the amendment**
- **after adoption all applicants will be notified on the same day**

Trade: Article 14 is replaced in its entirety by the following

- **Trade in PET continued for six months from publication of Register**
- **Application before the end? Then until Decision on authorisation**
- **All other plastics allowed until new proposal covering those plastics**
(3rd part of the discussion)

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B: Obligations

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new/changed Obligations under R 282/2008

Article 3a: General conditions for the operation of a recycling process

- **Requirement on quality assurance on the process and input material**
- **Conditions on technical suitability of the process**
- **Administrative conditions**

*Article 4, conditions for authorisation is simplified, will refer to 3a
(the Article is simplified, not the conditions)*

Article 6: clarification of authorisation holder and recycler

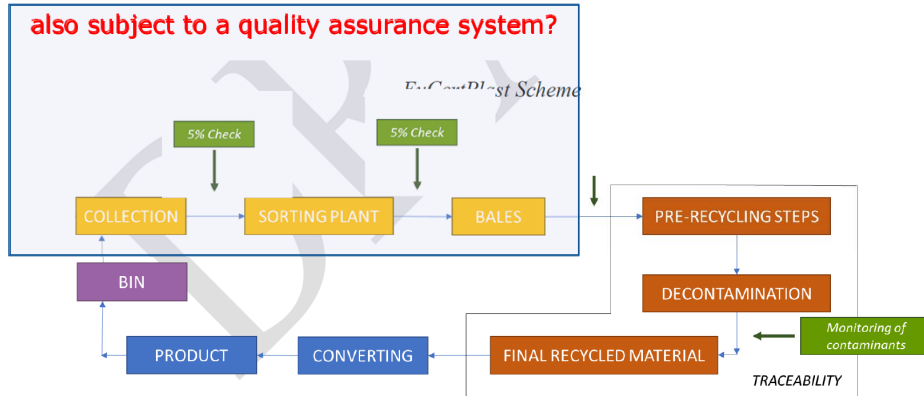
- **also under definitions**

18

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Or, graphically the question is



scheme from Plastic Recyclers Europe

- modified for discussion

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Quality of input material

Clear constraints on input material

- 5% non-food consumer PET
- 10/2011, non-industrial
- not overly polluted

These constraints must be

- met in practice
- enforceable

No realistic analytical approach

→ control in supply chain

- i.e. collection system

Possible solution to the right:

(b) the plastic input to the recycling process shall meet the following quality criteria:

- it shall originate only from plastic materials and articles that have been manufactured in accordance with Regulation (EU) No 10/2011; and,
- it shall originate only from plastic used by consumers or food business operators; and,
- it shall be collected with a waste collection system that is designed and organised to minimise incidental contamination with plastics used for purposes other than for contact with food, and with chemicals and plastics from other waste streams.

Plastic materials from a non-food and/or industrial origin and incidental contaminants shall only be present in minor and unavoidable amounts. The maximum level of incidental contamination and the composition of the input materials shall be in accordance with an Authorisation Decision, if applicable.

(c) For the purpose of point (b) the collection of the input materials shall be controlled by means of a **certified quality assurance system throughout the whole collection chain**. Article 3, 4, 5, 6, and 7 of Regulation (EC) No 2023/2006 shall apply mutatis mutandis to all stages of the collection chain of input materials;

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new/changed Obligations under R 282/2008

Article 7: general obligations arising from the authorisation

- **Clarification of responsibilities along the supply chain**
- **Administrative practices for authorisation holders**

Under study, suspension and revocation mechanisms in Article 8

- **how would official controls affect on-line registries?**
- **potentially provisions for suspension and revocation due to official controls**

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new/changed Obligations under R 282/2008

Article 9a and ANNEX III: compliance monitoring summary sheet

- **CMSS must be present two weeks after notification**
- **Provide the sheet within on month to competent authority**
- **the CA shall verify 'without delay', including an inspection**
- **authorisation suspended after one year if no agreement**
- **Union register shall indicate it is validated**

Article 10 Official controls

- **CMSS starting point for controls/audits**

Article 10a: Non-compliance

- **principle:**
if the operation of the process is not compliant,
the material cannot be placed on the market

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new/changed Obligations under R 282/2008

Article 11: Explicit labelling requirements added via Annex IV

- **requires and sets requirements to label conditions in the field of application**

Article 12: DoC

- **no real change to the Article (updated reference now to Regulation 10/2011)**
- **Annex 1.A updated to better meet different cases in supply chain**
- **Annex 1.B updated to be more comprehensive**
- **considering a template based approach, also for Regulation 10/2011**

C: Other Plastics

A different approach for all plastics other than mechanically recycled PET



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potential approach new/changed Obligations under R 282/2008

Article 1: Scope

- **Paragraph 2 deleted, all plastic recycling processes (for FCM) are in the scope**

Article 3: Not all processes would require authorisation

- **process offcuts**
 - **closed-loop (!)**
 - **plastics behind a functional barrier**
 - **plastics made from monomers produced by feedstock recycling (+ definition)**
 - **processes for which the Authority indicated no specific evaluation is necessary**
- **Subject to material specific rules in annex**

All other processes than still require authorisation

- **including most chemical recycling processes**

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potential approach new/changed Obligations under R 282/2008

Article 5: application for authorisation

- technical dossier on the basis of the scientific criteria the Authority applies
- for mechanically recycled PET this is 2011 opinion
- If they do not exist they must be established in accordance with Article 5a

Article 5a: Establishment of evaluation criteria for specific recycled plastic materials

- Would set out detailed procedure for an applicant and EFSA to follow
- step 1: consortium/association applies to establish criteria
- members of the consortium may place plastic on the market in limited amounts
- Authority to get lumped sum of three years
- step 2: once criteria are published applicants shall immediately apply
- Unless the authority states that individual evaluation is not needed, in this case the commission will lay down material specific rules.

27

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potential approach new/changed Obligations under R 282/2008

Lastly, amendment to Article 8 of Regulation (EU) No 10/2011:

“Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request. Substances originating from plastic recycling shall be manufactured in accordance with Regulation (EC) No 282/2008”

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summary/approach

Amendments A, Transition

PET only

Amendments B, Obligations

Together in amending text; aim Q2 2020

Individual Decisions; aim Q3 2020

Amendments C, other plastics later → more discussion needed, likely 2021

Texts ready for consultation later this month

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new measure on

GLYMO

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[3-(2,3-epoxypropoxy)propyl]trimethoxy silane

FCM No 1068, "Glymo"

- **Authorised for treatment of glass fibres that are added to reinforce low diffusivity plastics, residual content limit in the glass fibre, no SML**

Glymo is potentially genotoxic

- **known for significant time, but only above authorisation triggered action**

Safety

- **should not migrate**
- **10 ppb 'limit' is not sufficient**
- **0.15 ppb for Glymo + reaction products more appropriate, too low for SML**

Glymo is used for other purposes as well

- **10 ppb ND approach may be used, but insufficient**

Situation is not acceptable → measure

31

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Glymo measure

Under preparation, text being drafted at technical level

- **quick progress expected, but main discussions still taking place**

COMMISSION REGULATION (EU) .../...
of **XXX**
establishing a list of authorised substances and special conditions of use for [3-(2,3-epoxypropoxy) propyl]trimethoxy silane ("Glymo") with FCM No 1068 and with CAS No 2530-83-8 and similar epoxy silanes applicable to the manufacture of food contact coatings, adhesives, printing inks, silicones, paper and board, rubber, combinations thereof and combinations with plastics and/or inorganic substances

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Approach

Scope concerns the use of epoxy silanes, in,

- **silicones, paper and board, rubber, coatings, adhesives and printing inks**
- **and in combination/composite with most other materials**
- **not applicable to additives in plastic materials**

Epoxy silane given a 'wide' definition by functional groups

- **includes molecules with an epoxy and a silane functional group**

Union list with essentially two possibilities

- **genotoxicity is excluded and analytical approach available → SML**
- **no further information on toxicity**
→ **limited to specific use that is shown to be safe**
(as for Glymo under 10/2011)

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Transition

Likely short transition period, several months

Potentially also a mechanism to remain on the market

- **Provide a clear and well justified argument that the use is safe**
- **Apply to EFSA on that basis**
- **Remain on the market until Commission Decision**
- **Public register**

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Some examples of the drafting approach

Subject to change, just to give an idea

Table 1.a

- If a migration limit can be established, similar to Regulation 10/2011

Table 1.b

- Listing on the basis of a specific use (next slide)

OTHER NOTES ON THE VERIFICATION OF COMPLIANCE AS SET OUT IN TABLE 2.6 OF THIS ANNEX.

Table 1.a

(1)	(2)	(3)	(4)	(5)	(6)	(7)
FCM substance No	CAS No	Substance Name	SML	SML(T)	Restrictions and specifications	Verification of Compliance
XX1						
XX2						

35

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Table 1.b
NOTE: Substance 1068 is added for example only Table 1.b will be empty at the first adoption of this measure

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
FCM substance No	CAS No	Substance Name	Use No	Description of manufacturing method	Restrictions on manufacturing method	Description of final material and/or article	Conditions of use in food contact
1068 EXAMPLE ONLY	2530-83-8	[3-(2,3-epoxypropoxy)propyl]trimethoxy silane ("Glymo")	I	See Regulation (EU) No 10/2011 for comparison A: substance 1068 is manufactured B: substance 1068 is added as a component in a sizing agent for treating glass fibres C: the sizing agent is applied to treat glass fibres D: the glass fibres are embedded in a plastic material	A: no restrictions B: no restrictions C: In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for the substance and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer) D: to be embedded only in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinyl ester)	low diffusivity plastic material which contains for the purpose of its reinforcement embedded glass fibres	All foods
			II	A: substance 1068 is manufactured B: it is added to an adhesive preparation C: that adhesive is used between an layer of EVOH and a layer of PET D: the plastic material is converted into pouches for food packaging E: the pouches are filled and heat-sealed	A: no restrictions B: the adhesive preparation shall be stabilised to prevent hydrolysis of the substance; it shall expire within 3 months after manufacture C: the EVOH layer shall be of a minimum thickness of 20 µm, the PET layer 50 µm, and the adhesive layer 1 µm. D: the EVOH layer shall be on the inside of the packaging E: heatsealing shall not exceed a maximum temperature of 200°C for 2 seconds	Double layer flexible pouches in which the inner layer is EVOH and the outer layer pp	to be used for storage of refrigerated fresh cut or non-cut fruits and vegetables, dry or with an aqueous surface layer, for a maximum of 10 days at a maximum S/V ratio of 12

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Declaration of Compliance

New approach

- supporting documentation must exist
- template based approach
- possibly reference to MS register (Art. 10(2) of R 2017/625)
- details being studied
- first page on right

ANNEX 2
Template for Declaration of Compliance

DECLARATION of COMPLIANCE with REGULATION (EU) 2020/XXXX

I, the undersigned in section 4 declare in name of [ADD NAME OF MANUFACTURER] as identified in section 1.1, that the product identified in section 1.2 contains an epoxy silane and is subject to Regulation (EU) 2020/XXXX; I hereby declare on the basis of my analysis to which I keep supporting documentation available to competent authorities of the Member States and can be requested via the contact point mentioned in section 1.1.4, and the information provided in section 2 that this substance is used in full compliance with all provisions of Regulation (EU) 2020/XXXX, provided it is used subject in accordance with section 3 of this declaration, to which purpose I provided adequate instructions and labelling on the product.

I claim full responsibility for the contents of this declaration and for ensuring the compliance with Regulation (EU) 2020/XXXX, this declaration shall apply in full until the date set in section 5, or until a relevant amendment of Regulation (EU) 2020/XXXX invalidates it, or until I recall this declaration.

Section 1 Identification					
1.1 manufacturer		1.2 product		1.3 competent authority	
1.1.1 name		1.2.1 main name		1.3.1 name	
1.1.2 address		1.2.2 trade-names		1.3.2 address	
1.1.3 country		1.2.3 epoxy silane		1.3.3 country region	
1.1.4 contact		1.2.4 other info		1.3.4 reg. number	

Section 2: Compliance

2.1 basis for authorisation (tick one box)

2.1.1	<input type="checkbox"/>	Table 1.a of Annex I	Applicable SML	
2.1.2	<input type="checkbox"/>	Table 1.b of Annex I	Use No + step	
2.1.3	<input type="checkbox"/>	Transitional provisions	EFSA Q number	

2.2 migration testing results (apply only in case 2.1.1 or 2.1.3 is marked)

2.2.1 test results	
2.2.2	

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Further steps

Text being finalised, thereafter consultation with Member States

- vote as soon as procedure allows

For time being everything being tentative

38

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Update on

PHTHALATES

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Timeline

Mandate from Commission to EFSA July 2017

- **New scientific information available since the 2005 EFSA opinions and evaluated recently by ECHA (reprotoxic effects)**
- **EFSA asked to evaluate whether authorisations for DEHP, DBP and DIBP are still in accordance with FCM Regulation**

Update to mandate May 2018

- **To allow for consideration of potential relevance of exposure to other phthalates – DINP and DIDP also authorised in plastic FCM**

EFSA public consultation February – April 2019

- **Dedicated consultation webpage**
- **Webinar**

40

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Next steps

EFSA currently concluding on the updated risk assessment work

- **EFSA created a dedicated Working Group to undertake the work**
- **EFSA has carried out the work in close collaboration with the European Chemicals Agency (ECHA)**
- **Two main outputs: (1) technical report on the consultation and (2) updated scientific opinion**

Commission will base its risk management of phthalates in FCMs on EFSA opinion

- **Only once the opinion is available and has been published**
- **The opinion is scheduled to be adopted at the September CEP Plenary session**

Commission will shortly invite stakeholders to take part in a questionnaire as regards the use of phthalates in FCMs