Committee Product Policy

22 / 04 / 2020

AGENDA

1. Welcome
2. Do's and Dont's
3. Approbation of the minutes of the previous meeting and agenda
4. Priorities of the participants
5. Review Framework Regulation 1935/2004
6. Update on Council of Europe
7. Auto Control Guide
8. FDA legislation on FCM for recycled PB
9. AOB
   - ✓ SUP-directive: most important conclusions of the draft guidance
   - ✓ Substances of interest
   - ✓ Packaging Ink Joint Industry Taskforce
10. Date NEXT MEETING
11. Tour de Table

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DO'S ✓

ENSURE STRICT PERFORMANCE IN AREAS OF:

Oversight / supervision:

- ☑ Have a secretariat representative at each meeting;
- ☑ Consult with appropriate counsel on all questions related to competition law;
- ☑ Limit meeting discussions to agenda topics;
- ☑ Provide each attendee with a copy of this checklist, and have a copy available for reference at all meetings.

Recordkeeping:

- ☑ Have an agenda and minutes which accurately reflect the matters which occur;
- ☑ Ensure the review of agendas, minutes and other important documents by appropriate staff or counsel, in advance of distribution;
- ☑ Fully describe the purposes, structures and authorities of the groups.

Vigilance:

- ☑ Protest any discussion or meeting activities which appear to violate this checklist;
- ☑ Ask for those activities to be stopped so that appropriate legal check can be made by counsel;
- ☑ Disassociate yourself from any such discussion or activities and for the attendees, leave any meeting in which they continue (and have it minuted)

DONT'S X

DO NOT, IN FACT OR APPEARANCE, DISCUSS OR EXCHANGE INFORMATION NOT IN CONFORMITY WITH COMPETITION LAW, INCLUDING FOR EXAMPLE ON:

Prices including:

- ☒ Individual company / industry prices, price changes, price differentials, discounts, allowances, credit terms, etc.
- ☒ Individual company data on costs, production, capacity (other than nameplates capacities), inventories, sales, etc.

Production, including:

- ☒ Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers;
- ☒ Changes in industry production capacity (other than nameplates capacities) or inventories, etc.

Transportation rates:

- ☒ Rates or rate policies for individual shipments, including basing point systems, zone prices, freight, etc.

Market procedures, including:

- ☒ Company bids on contracts for particular products; company procedures for responding to bid invitations;
- ☒ Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them, etc.
- ☒ Blacklist or boycott customers or suppliers

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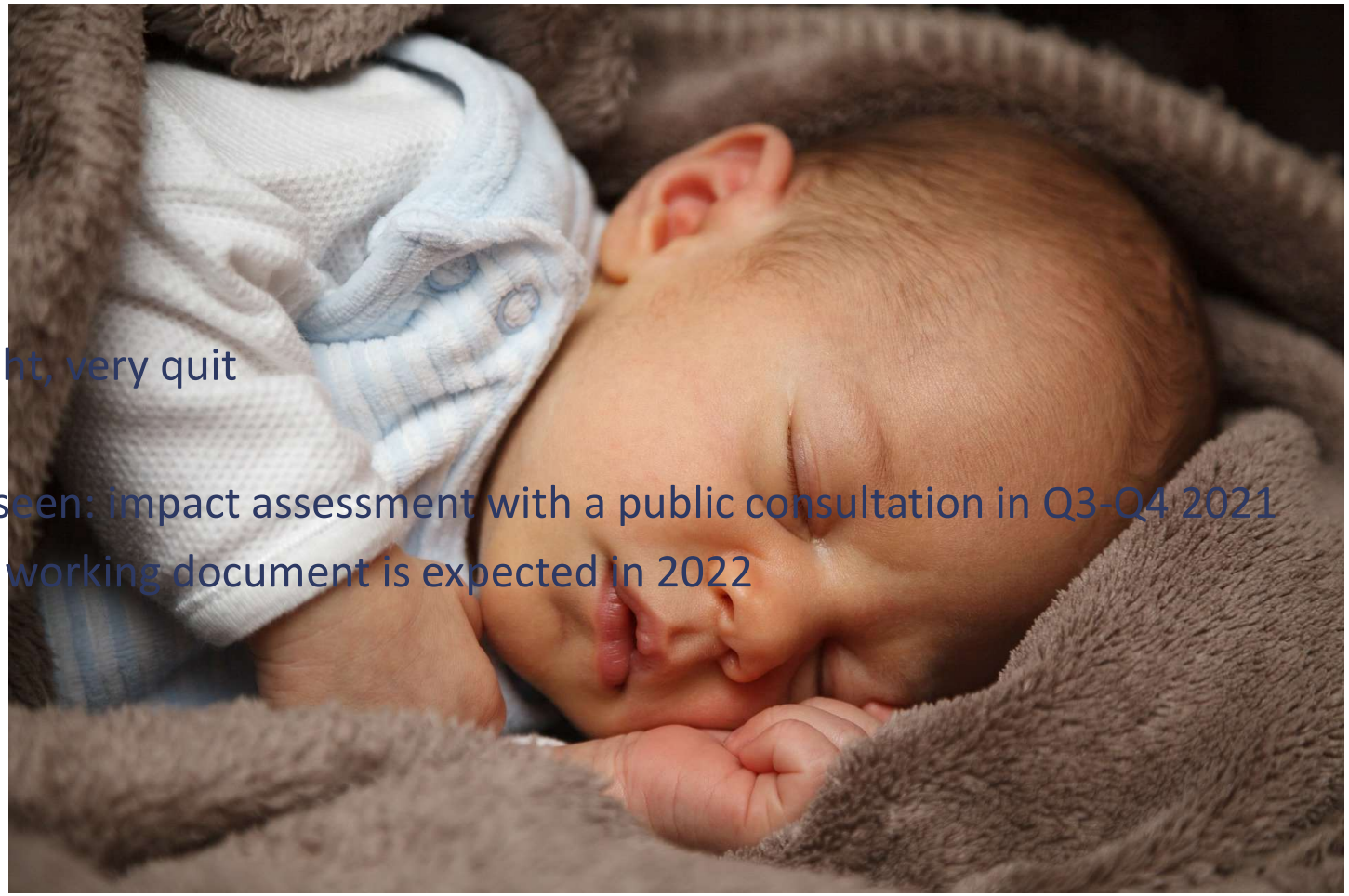
REVIEW FRAMEWORK REGULATION 1935/2004



- Sssssht, very quit

- Foreseen: impact assessment with a public consultation in Q3-Q4 2021
- Staff working document is expected in 2022

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COUNCIL OF EUROPE: GUIDES ON FCM & PB FCM

1. Guiding Principles for FCM/A
2. Technical Guide on P&B materials and articles for food contact

Harmonisation	**Specific demands**	**Responsabilities are seperated for the whole value chain**	**Industry self assessment**
Food Contact Industry guideline is consulted in the drafting	**A start on what consists as adequate information**	**A few values are too sharp**	**Cleaning of fibres??**

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Council of Europe - Documents

Relatively balanced

Some overlap with 1935/2004

- Takes precedence over the resolution

Mutual recognition prevails

- Should be taken up in the texts

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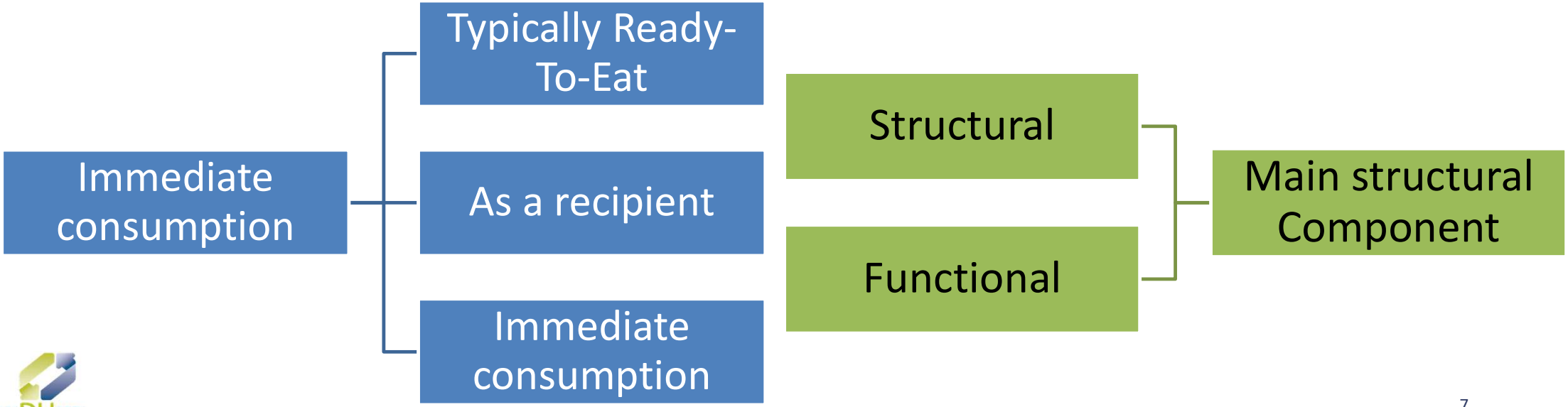
Single Use Plastics Directive

- Nationale omzetting – Juli 2021
- Guidance on single use plastic products – Juli 2020
  - ✓ CITPA interview met de consultant
  - ✓ Focus on “main structural component” and “immediate consumption”
- EU methodology for calculation of reduction targets – 2021



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AUTO CONTROLE GUIDE

Version 6 send to FASFC (FAVV/AFSCA)

Report with several remarks (legislative, clarifications, much input)

Biggest remarks on Risk and Compliance Assessment

- Recycled material (chapter to be included)
- HACCP (CCP → chapter must be made)
- Further development of the specific risks

ALL INFORMATION ON HACCP and CCP IS WELCOME!

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SUPD

- Ramboll DRAFT guidance published
- 17/04 → remarks by the associations on the text
- 24/04 → remarks by the MS on the text

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INDUFED POSITION

- Cellulose is a natural unmodified polymer
- Structural is not the same as Functional
- Main component should be taken into account
- Single portion is for 1 person only

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SUBSTANCES OF INTEREST

Name	EC no.	CAS no.	Date of inclusior	Intrinsic property(ies) referred to in Article 57	Infocard
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-	16/01/2020	Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health)	
Diisohexyl phthalate	276-090-2	71850-09-4	16/01/2020	Toxic for reproduction (Article 57c)	
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	16/01/2020	Toxic for reproduction (Article 57c)	
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	16/01/2020	Toxic for reproduction (Article 57c)	Can be found in paper product

For your information:

- If a SVHC is present in an article in a concentration higher than **0,1% (w/w)**, the producer of that article must inform its customers on the presence of the substance and with enough information on the safe use of the article.
- If the total amount of that substance present in all articles produced that contain more than 0,1% (w/w) of the substance exceeds **1 t/year/actor**, ECHA must be informed as well.

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FDA Regulation of Recycled Paper and Paperboard for Food-Contact Applications

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FDA REGULATION FOR RECYCLED P/B FOR FCM/A

Primary FDA Paper Regulations

- 21 C.F.R. § 176.170 ("Components of paper and paperboard in contact with aqueous and fatty foods")
- 21 C.F.R. § 176.180 ("Components of paper and paperboard in contact with dry food")

No "free" fat
→ Flour
→ Sugar

But note that ALL of Part 176 pertains to paper!

FDA REGULATION FOR RECYCLED P/B FOR FCM/A

Section 176.170

Lists substances permitted for use in food-contact paper

- 1 - Compositional requirements

Includes extractives limitations that apply to finished paper

- 2 - End-test requirements

TESTING 1 ≠ 2

Compliance with BOTH

FDA REGULATION FOR RECYCLED P/B FOR FCM/A
COMPLIANCE VS. MIGRATION TEST

Compliance tests or "end tests" apply to substances already cleared by FDA

- For paper, end tests are described in Section 176.170(c)

Migration tests are conducted to establish compliance for a new food-contact material, or to expand the use of an existing substance

- *See:* FDA's Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations

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Compliance vs. Migration Test

Compliance Test	Migration Test
Characterization test based on gross extraction or solubility	Simulates migration to food
Used to determine compliance of cleared substance with applicable regulation	Used to determine migration of uncleared substance
Protocol described in the regulations, *e.g.*, 21 CFR 176.170	Protocol is *not* described in the regulations; described in Guidelines
Usually measures total extractives from food-contact article	Usually measures specific migration of uncleared FCS
Sensitivity often relatively crude (*e.g.*, 50 ppm in food)…similar to an overall migration limit (OML)	Analyses are usually very sensitive (*e.g.*, 50 ppb in food)

FDA REGULATION FOR RECYCLED P/B FOR FCM/A

Recycled Paper – Relevant Regulations

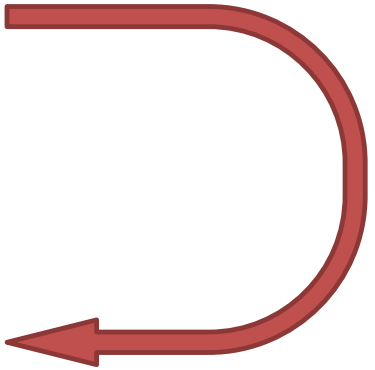
- 21 C.F.R. § 176.170 ("Components of paper and paperboard in contact with aqueous and fatty foods")
- 21 C.F.R. § 186.1673 ("Pulp")
- 21 C.F.R. § 176.260 ("Pulp from reclaimed fiber")

Post-industrial (in-plant scrap)

- If safe
- Safe if scrap was safe

Post-consumer

- If safe
- Impurities!



FDA REGULATION FOR RECYCLED P/B FOR FCM/A

Establishing Safety of Impurities

NOL

- Batch testing
- Surrogate testing

Self-Determination

- Source control
- Routine chemical contaminant testing
- Surrogate testing

Safety assessment is needed

FDA REGULATION FOR RECYCLED P/B FOR FCM/A

Safety assessments are based on:

- Chemical identity of impurity
- Level of impurity in paper
  - Is it well-controlled or does it vary?
- Potential migration of impurity to food
- Dietary exposure to impurity from migration to food
- Toxicity of impurity

Consider impact of intended use on migration/exposure

- Polymer coatings might reduce migration
- Dry-food-only applications might allow for a narrow focus on volatile and semi-volatile impurities

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General Toxicology Approaches

- Evaluate the scientific literature on the substance of interest
- If substance is genotoxic, FDA suggests < 50 ppt exposure
- If an unintentional impurity is potentially carcinogenic, conduct cancer risk assessment based on tumorigenic potency data (target risk < 1×10^{-7} or 1×10^{-8})
- Otherwise, use the data available in the published literature to establish an Acceptable Daily Intake (ADI)
- Exposures should only be a small fraction of ADI or URF

FDA REGULATION FOR RECYCLED P/B FOR FCM/A

- If calculation is not satisfatory → TESTING

- Migration Testing:

Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations (April 2002; December 2007) *(https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/guidance-industry-preparation-premarket-submissions-foodcontact-substances-chemistry)*

FDA does not CONTROL

and does not establish a CONTROL PROGRAM

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THANK YOU FOR YOUR ATTENTION

Next meeting

- 18/09 – 09/12
- inDUfed?

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Extra Slides