# EFSA Technical Report 2023:

"Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials"

- Application to paper and board

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# IN THE CONTEXT OF THIS SESSION

Background:  safety assessment, challenges, commonalities and differences

CoE Technical Guide on paper & board

Manufacturing virgin paper & board

Converting virgin paper & board

Safety of virgin paper & board according to Industry

- **This presentation**

# ‘PAPER’ IN THE CONTEXT OF FCMs and the TR

With the exception of coffee filters etc,

Paper/Board FCMs are rarely if ever ‘just paper’

| Paper / Board | Of natural origin (but not a food source) |
|---|---|
| Making pulp | e.g. NaOH and $Na_2S$ cooking in a Kraft process |
| Impurities from any recycled content | ex-FCM substances but also others |
| Paper-making chemicals | Not retained intentionally e.g. processing aids |
| Paper-making chemicals | Retained intentionally e.g. additives |
| Coatings | e.g. clay + binder |
| Inks | question of set-off or through- migration |
| Adhesives | |

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Knowns: Will require separate evaluation.

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# ‘PAPER’ IN THE CONTEXT OF FCMs and the TR

Mixtures of natural origin used to make FCMs

Our topic here

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What is in the technical report? (that may be useful here)

# CHARACTER OF THE TECHNICAL REPORT

## "PRINCIPLES THAT COULD BE APPLICABLE TO THE SAFETY ASSESSMENT OF THE USE OF MIXTURES OF NATURAL ORIGIN TO MANUFACTURE FOOD CONTACT MATERIALS"

EFSA can issue a Technical Report at the request of the Commission, on **its own initiative** or as foreseen in relevant sectoral legislation. .... Technical Reports are, as a general rule, **prepared by an EFSA working group and/or by EFSA scientific staff**.

A TR is a document that describes the nature, **state of the art, progress, or results of a technical process** and pertains for example to: (i) the collection and analysis of comments received via public consultation; (ii) an Overall Opinion on GMO applications[6]; (iii) **the collection and analysis of experiences and approaches in EFSA, Member States and wider**; (iv) an annual report of network activities; (v) a final report from an EFSA project; (vi) administrative guidance; (vii) a note for guidance; (viii) a manual for the use of reporting applications and for reporting of data through EFSA data collection systems; (ix) or technical specifications to developed IT-based reporting systems.

https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions

# TECHNICAL REPORT: CONTEXT

Substances / Mixtures of natural origin used to make FCMs

Substances from renewable biological resources may be single substances or well-defined mixtures of identified substances, but more commonly they are complex mixtures – in ECHA terminology called UVCB substances (Unknown or Variable Composition, complex reaction product, or Biological materials).

They may  be considered synonymous with ‘natural’ and ‘safe’ (or at least ‘safer’ than their synthetic counterparts) but this is not necessarily the case.

These UVCB substances of biological origin may be obtained directly and be chemically unchanged.  However, the production process may result in modification of the constituents, either unintentionally or intentionally, to make the product more suitable for its intended use in the FCM.

# HOW DOES P/B FIT WITHIN THAT CONTEXT?

Substances / Mixtures of natural origin used to make FCMs ✓

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# APPLICATIONS ON PLASTIC FCS INFORMED THE TR

Assessment of plant-based additives (fillers) had framed the TR.

Plants are made of complex mixtures with variability in the nature and the level of constituents

A fraction is identified and (semi-)quantified

A fraction ‘may’ not be identified and/or quantified and/or LoD> TTC of 0.15 µg/kg food (0.0025 µg/kg bw pd). This uncharacterised fraction makes the assessment more complex and uncertain.

Plants are natural and may be food or close to food. This may waive the need for some or all tox data and simplify the assessment.

Two case studies that informed the TR:-

# GENERIC MANDATE: FCM NO 96
# UNTREATED WOOD FLOUR AND FIBRES (CEP PANEL 2019)

Wood cannot be considered inert per se owing to the many low molecular weight substances it contains, and when migrating into food, the safety of these constituents must be assessed.

### 3.2. Criteria for future evaluations of wood and similar materials from plant origin as additives for plastic for food contact applications

Seeing the variability in composition and the possible presence of toxic substances in some woods, the safety of wood and similar materials from plant origin as additives for plastic FCM should be evaluated as for any other additives following the EFSA Note for Guidance (EFSA, 2008). Specifically, the following aspects should be considered:

- species;
- possible variability related to age, growth conditions and geographical origin;
- treatment during cultivation/storage;
- manufacturing from the source material into the additive: physical and mechanical processing, chemicals used in this process;
- substances used together with the additive to produce the plastic material, e.g. coupling agents;
- comprehensive analysis of the low molecular weight constituents below 1,000 Da (1,500 Da for poly- and per-fluoro compounds; EFSA, 2016), including contaminants;
- migration of substances resulting from using the additive, comparing samples made with and without the additive;
- toxicological data covering the migrating substances detected in this analysis.

## APPLICATION FOR ADDITIVE TO BE USED IN PLASTIC FCM: BLEACHED CELLULOSE PULP FROM PINE & SPRUCE (CEP PANEL 2022)

Main findings

No tox data were provided for the substance as its migration is not expected (HMW)

The process is not sufficiently specified to assume that the composition of all bleached cellulose pulp samples will be the same as the ones investigated.

The safety of the potentially migrating LMW substances detected was addressed individually and was considered adequate. (*CPA- component-based approach*)

Not all possibly migrating substances were identified or amenable to the analytical methods applied

LoDs not low enough to ensure absence of potentially genotoxic substances at a concentration leading to an exposure >TTC..

The analysis was insufficient owing to a substantial fraction of unidentified components.

- All components <1,000 Da potentially migrating …must be assessed individually or as a mixture. The single chemical approach may be inadequate for the evaluation of complex mixtures containing a substantial fraction of unidentified components.

# MAIN ELEMENTS OF THE TR

(Mixtures from) natural sources are not safe *per se*.

Uses and assessment of natural compounds/complex mixtures triggers additional uncertainties especially regarding the safety of the uncharacterised fraction.

All components <1,000 Da must be assessed individually or as a mixture according to EFSA Guidance documents.

Waiving part of the data requirements for substances derived from edible food sources is acceptable. If modified, the modifier and new substances formed should be assessed.

# EFSA GUIDANCE ON ASSESSING MIXTURES

EFSA SC guidance on mixture is a combined approach:

CBA – Component Based Approach is preferred. For identified chemicals. Tox studies, literature, read across, Cramer Class, TTC, in silico.

WMA - Whole Mixture Approach relies on consistency of the mixture, is useful, but has significant limitations (esp wrt gentox and tokicokinetics)

A combined approach may be used/necessary: CBA for those substances identified and WMA for the uncharacterised fraction (which should be as low as possible)

- Identity & composition are key. Variability / Uniformity is critical. An exhaustive analysis of the migrating/migratable LMWF is crucial.

## TECHNICAL REPORT 2023:
## THREE CASES FOR MIGRATION AND TOX DATA REQUIREMENT

It is proposed to waive toxicological data requirements for:

~~1. Substances that are consisting of- or derived from- edible food sources.~~

2. If the source material is not a food and if a substance of concern is also found in the normal diet, exposure arising from the proposed FCM use should be compared with the existing dietary exposure and any additional exposure should not be more than minimal.

3. If there is a substance of concern in the mixture that does not occur in the normal diet and if the substance is a component of the food contact mixture, a standard safety assessment according to the existing guidelines should be applied. For migrating impurities or contaminants, alternative approaches may be applied such as using a TTC approach.

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Even if not identical, this may allow for read-across to similar substances found in plant materials that are food?

# TR IS APPLICABLE TO P/B AS FOR OTHER MIXTURES OF NATURAL ORIGIN

Some consensus is needed:

Thorough compositional characterisation “as fully as possible” - what does this mean?

The assessment of NIAS is more conservative in FCM than in other areas.

Measuring 0.15 µg/kg food (corresponding to the lowest TTC) is often technically unfeasible

Burden of proof - is it reasonable to assume (unless demonstrated otherwise) that every 'peak' is genotoxic.

The safety level could be calibrated against that for foods => possible rôle for risk managers to set a safety level.

# TECHNICAL REPORT 2023:
# THREE CASES FOR MIGRATION AND TOX DATA REQUIREMENT

So in conclusion, the TR is fully applicable to P/B:

“Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials.

- Certainly no panacea.
- P/B is not food so some of the provisions are not available.
- No exemption from chemical analysis, identification and evaluation.
- Points the way to how safety can be evaluated and thus the data needed to support that evaluation.