STATE OF THE DISCUSSIONS AND OUTCOME AT THE FCM NETWORK (2014–2024) ON PAPER AND BOARD FCM

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OBJECTIVES

Present state of the discussions and outcome at the FCM Network since 2014

I. **National regulations, approaches** related to **safety assessment**.

II. **National activities discussed** and topics currently under consideration.

Coe and EC JRC activities (see items 5 and 10).

ACTIVITIES ON P&B IN 9 MEMBER STATES

4 Countries with Formal Regulatory Frameworks and other activities

Italy, **Germany**, **The Netherlands, Belgium**

- Established national regulations with **positive lists** and **safety assessment** prior to authorisation.
- Different categorisation by material/use.
- Basis for the safety assessment is the EFSA Note for Guidance

5 Countries with other activities

France, **Denmark**, **Greece**, **Norway**, **Austria**

GENERAL OVERVIEW

Member State	Regulation	Positive-list structure	guidance
Italy	**Ministerial Decree 21-03-1973** (Annex II, Sec. IV) **+ Decree 03-06-1994**	1. **Part A** — **Constituents**: fibres, mineral fillers/pigments, functional additives, optical brighteners (total ≤ 0.3% w/w on dry, alone or in combination). 2. **Part B** — **Processing aids**: listed process aids with explicit purity/use/quantity limits and conditions of use. Colorants: handled via separate national provisions (not a "Part C" within paper & board).	**MoH + ISS**; dossiers per **EFSA Note for Guidance** (NfG)
The Netherlands	**Warenwetregeling** , Ch. II (Paper & Cardboard)	1. **General paper & board**: cellulose-based fibrous materials (incl. recycled). → Positive list + SML table for constituents/auxiliaries; Q: only cold? 2. **Warm / high-temperature use**: contact ≥ 80 °C up to boiling (e.g., hot filters, tea bags, cook-in-bag). → Separate positive list + SML table with conditions suited to hot use. (Baking scenarios are addressed by referencing requirements aligned with BfR 36/2.)	**Dutch authority**; dossiers per **EFSA Note for Guidance** (NfG)
Germany (BfR)	**BfR Recommendation XXXVI** series (XXXVI, /1, /2, /3) ~900 substances (*in XXXVI*)	1. **XXXVI: Paper and board for food contact** (food packaging, kitchen towels, napkins) (listed substance: 437) 2. **XXXVI/1: Cooking Papers, Hot Filter Papers and Filter Layers** (hot filter papers, tea bags, boil-in-bag packages etc.) (listed substance: 152) 3. **XXXVI/2: Paper and Paperboard for Baking Purposes** (baking paper, etc.) (listed substance: 201) 4. **XXXVI/3: Absorber pads** based on cellulosic fibres for food packaging (listed substance: 87)	**BfR**; dossiers per **EFSA Note for Guidance** (NfG)
Belgium	**Royal Decree 11-05-1992, Annex 4**	1. **Single positive list on** constituents: (1) **fibrous raw materials**, (2) **mineral fillers/pigments** (natural or synthetic, water-insoluble and non-hazardous), and (3) **auxiliary products**. Each subject to any stated conditions/purity limits	**Federal authority**; amendments by Royal Decree; / **EFSA Note for Guidance** (NfG)

Different approaches in the categorisation of the + lists (what basis, need for harmonization)
Safety assessment – a priori – acc. to EFSA NfG

GENERAL OVERVIEW

Member State	Regulation	Overall migration rule	Migration test
Italy	**Ministerial Decree 21-03-1973** (Annex II, Sec. IV) + **Decree 03-06-1994**	general **OM for non-plastic materials commonly set at 8 mg/dm² or 50 mg/kg**;	**Maximum amount or from migration** test for special P&B, eg. Fluorocompounds. From the **measured migration** (only when technically feasible) or **calculated** from the use level (**total transfer**)
The Netherlands	**Warenwetregeling**, Ch. II (Paper & Cardboard)	**OM = 10 mg/dm²** (with exceptions/expressions).	Dossiers include **migration studies in food simulants under conventional t/T conditions**, or the **worst-case approach** (100% migration of the residual content). For **General paper & board** → Compliance via migration testing or 100% transfer calculation (typical assumptions: 6 dm²/kg, 300 g/m²).
Germany (BfR)	**BfR Recommendation XXXVI** series (XXXVI, /1, /2, /3)	**no single generic OM value**; compliance is via **specific limits/criteria** (e.g., Pb/Cd in cold-water extract, Al = 1 mg/kg, PAAs DLs) and intended-use testing.	**Cold/hot-water extracts** (DIN EN 645/647); **Organic solvent extracts** (DIN EN 15519), **MPPO for dry/baking/volatiles** (DIN EN 14338); Paper-specific worst-case conventions (e.g., 6 dm²/kg; 300 g/m² grammage). Baking/microwave scenarios and thermostability checks are specified
Belgium	**Royal Decree 11-05-1992**, **Annex 4** (Paper & Board)	**OM ≤ 60 mg per 6 dm²** for paper/board in humid and/or fatty contact (explicit text in Annex 4).	Not presented during the Network

The number of application per year was not easily retrieved from the previous Network
Migration rules are not harmonised

JRC ACTIVITIES – 8TH NETWORK 2022

Paper & board

Coated/treated paper v.s. uncoated/untreated paper

Regulation (EU) No 10/2011 ⟵ ⟶ CEN “extraction” standards?

Food in contact with	Food Simulant/extraction media	Test Conditions	Ref
Dry, non fatty food	E	Real conditions of use	EN 14338
Aqueous food in contact with coffee filter, tea bags and cooking bags	Deionized water	2h @ 80°C “hot water extraction”	EN 647
Moist/Aqueous food and beverages (other app.)	Deionized water	24h @ 23°C “cold water extraction”	EN 645
All kind of food (baking application)	Deionized water	2h @ 80°C “hot water extraction”	EN 647
	E	2h @ 175°C [oven use] 0.5h @ 150°C [microwave use]	EN 14338
Fatty food	OS (95 % EtOH or Isooctane)	2h @ 20°C [short contact] 24h @ 20°C [long contact] 2h @ 60°C [cooking and baking application for any time contact]	EN 15519
	Deionized water	24h @ 23°C “cold water extraction”	EN 645

BFR RECOMMENDATIONS XXXVI – MIGRATION TESTING FOR PAPER & BOARD

- **XXXVI (finished paper) – Paper and board for food contact**
  - Cold-water extract: DIN EN 645
  - Organic-solvent extract (isooctane / 95% ethanol): DIN EN 15519
  - Migration tests: according to Regulation (EU) No 10/2011
  - Where appropriate: transfer using MPPO simulant — DIN EN 14338
- **XXXVI/1 (finished paper) – Cooking Papers, Hot Filter Papers and Filter Layers**
  - Hot-water extract: DIN EN 647
  - Organic-solvent extract (isooctane / 95% ethanol): DIN EN 15519
- **XXXVI/2 (finished paper / baking & microwave uses) – Paper and Paperboard for Baking Purposes**
  - Hot-water extract: DIN EN 647
  - Organic-solvent extract: DIN EN 15519
  - Or migration tests:
    - 2 h at 220 °C with MPPO (DIN EN 14338), or
    - 2 h at 220 °C with test dough (DIN 10955 §11.2.5.4)
  - Microwave-only use: 30 min at 150 °C
- **Thermostability (XXXVI/2, substance without paper matrix) – Paper and Paperboard for Baking Purposes**
  - TGA conditions: 220 °C/2 h; 250 °C/10 min; microwave 150 °C/30 min
  - Outcome: identify/quantify released volatile and decomposition products

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NATIONAL ACTIVITIES (1/7)

Italy

- **National monitoring campaigns** — >100 P&B samples from retail & online screened for inks, adhesives, phthalates, solvents, hydrocarbons. (Network #6, Jul 2018)
- **Evaluation of NIAS and chloropropanols** (**incl. extraction/migration approaches**) to strengthen hazard identification and align test strategies across MS. (Networks #1 & #6)

Germany

- **Oligomers from polymeric additives** — highlighted evaluation challenges (limits of conventional methods) and method-development work **to improve detection/assessment**. (Network #6, Jul 2018)
- **Printing inks in P&B** — BfR work on **safety evaluation of ink components**; concern about BPA in recycled fibres; call for appropriate migration testing for recycled-content papers. (Network #7, Nov 2019)

NATIONAL ACTIVITIES (2/7)

The Netherlands

- **NL–DE pilot** — harmonised Safety Data Sheets (SDS) for auxiliaries/refining agents — common data fields and dossier alignment to ease cross-MS evaluations. (EFSA FCM Network #6, Jul 2018): *How does that fit with the categorisation?*
- RIVM review on **MOAH/MOSH** — estimated contribution to total dietary exposure ~2%. (Network #6, Jul 2018)
- **Effect-based strategy for recycled P&B** — real-use migration (food simulants) vs exhaustive Soxhlet (acetone–methanol); exhaustive extracts showed effects at lower concentrations, giving a stricter NIAS/mixture screen. (Network #11, Aug 2024)
- **Bioassay battery in recycled P&B workflow** — cytotoxicity, mutagenicity, endocrine activity (EDC) with S9 metabolic activation; paired with food simulants (e.g., ethanol, acetic acid). (Network #11, Aug 2024)
- **Sample-prep & workflow harmonisation for recycled fibre** — practical protocols to combine migration + exhaustive extraction, aimed at **prioritising high-risk NIAS** in complex recycled streams. (Network #11, Aug 2024)

NATIONAL ACTIVITIES (3/7)

Belgium

- **NIAS**
  - **Printed-layer NIAS prioritisation (Sciensano project)** — focus on inks/adhesives in P&B; built an in-silico → in-vitro workflow to triage genotoxic candidates. (EFSA FCM Network #5, Jul 2017)
  - **Data-sharing push** — advocacy for an EU-wide **NIAS database** (structures, identifiers, analytical markers, hazard flags, decision rules) to support harmonised risk assessment and transparency across Member States. (Network #5, 2017)
  - **A non-animal screening approach** that uses four **QSAR models**, literature checks, and confirmatory Ames tests to **identify** and **rank genotoxic NIAS** in inks/adhesives; 106 substances screened, 19 flagged for follow-up (Network #6, 2018)
  - **Methodological development** — provides a risk-based **prioritisation framework for poorly characterised NIAS** from printed/laminated P&B; scalable to other MS and to supply-chain assessments. (Network #7, 2019)

NATIONAL ACTIVITIES (4/7)

France

- **NIAS**
  - **DTU–ANSES joint project (semi-quant for NIAS in P&B)** — LC-ESI-MS workflows to estimate response factors without standards; integrates **QSAR-based modelling to improve semi-quantification and risk ranking**. (EFSA FCM Network #2, Jul 2015)
  - **ANSES decision trees for NIAS** — tiered risk-prioritisation **using TTC** (Thresholds of Toxicological Concern) to handle substances with **unknown identity/toxicology**, enabling evidence-based decisions under uncertainty.
  - **Large-scale NIAS screening/prioritisation** —> 60 unknown migrants from P&B screened and triaged; delivers sharable methods/tools for MS, fostering methodological harmonisation through science rather than legislation.
- **Methodological** emphasis on analytical capability building (advanced LC-MS), risk frameworks (TTC, QSAR), and workflows that other MS can adopt for P&B evaluations.

NATIONAL ACTIVITIES (5/7)

Denmark

- **NIAS**
  - **Research-driven NIAS strategy**: **Bioassay-guided** chemical analysis to identify **unknown migrants from P&B**; in-vitro assays integrated with targeted analytics. (Network #1, 2014)
  - **FR–DK semi-quant LC-MS project**: Response-factor/QSCoR tools to **support semi-quantification of NIAS** from P&B. (Network #2, 2015)
- **PFAS**
  - measure & workflow: **National recommendation 0.35 µg/dm²** total organic fluorine; stepwise QSAR + effect-directed in-vitro panel for assessment. (Network #3, 2016)
  - market surveillance impact — **national data** show a marked **decline in PFAS-positive samples in P&B over time** (e.g., from ~60% in 2009 to ~4% in 2013), highlighting the effectiveness of focused controls. (timeline shown in DK updates)
  - **migration data: High-T studies on P&B** into food simulants (20%/50% EtOH) and real foods (e.g., porridge, soup) to inform exposure estimates. (Network #8, 2022)

NATIONAL ACTIVITIES (6/7)

Greece

- **PFAS**
  - **method development**— confirmed PFAS occurrence in the absence of EU/national MLs; highlights the need for systematic monitoring and data for future risk-management. (Network #11, Aug 2024)
- **Screening of recycled P&B**: Targeted + suspect UPLC-qTOF workflows to map migrants (bisphenols incl. BPA, PAAs, photoinitiators) and build contaminant profiles. (Network #8, 2022)
- **Methods & comparability**: Adaptation of HS-SPME-GC-MS/MS and LC-MS/MS to P&B matrices; contribution to method validation and inter-lab data comparability. (Network #8, 2022; Network #11, 2024)

NATIONAL ACTIVITIES (7/7)

Norway

- **National PFAS monitoring in paper-based FCM** (EFSA FCM Network #11, Aug 2024)
- **Network signal (EFSA FCM #11, Aug 2024)** — highlighted the **absence** of EU-wide **limits for total fluorine in P&B** and called for harmonised thresholds to enable preventive action and alignment across Member States.

Austria

- **Network signal (EFSA FCM #11, Aug 2024)** — Austria called for updating P&B assessment frameworks in light of the EFSA 2023 technical report on natural compounds and recent science.
- Austria accepted **to lead the update of the assessment of paper and boards** (harmonisation between MS)

MS CONSIDERATIONS

Activity	Countries involved
PFAS	**Denmark**: TOF 0.35 µg/dm²; high-T migration (20/50% EtOH, foods); **Greece**: HS-SPME-GC-MS/MS method; PFAS occurrence noted; **Norway**: National PFAS monitoring in paper-based FCM; call for TF thresholds.
NIAS	**France–Denmark**: Joint semi-quant LC-MS project for P&B NIAS; **Italy**: Monitoring campaigns (>100 P&B samples; inks/adhesives/solvents/hydrocarbons); **The Netherlands**: Effect-based assessment of recycled P&B (migration vs exhaustive extraction). **Belgium**: in printed-layer, specific database, non-animal screening approach
Bioassays / effect-based approaches	**Denmark**: Bioassay-guided strategy for "unknowns"; stepwise QSAR + in-vitro panel; **Belgium**: QSAR + literature + Ames to rank genotoxic NIAS in printed layers; **The Netherlands**: Battery of in-vitro bioassays (incl. S9) on recycled P&B.
Printing inks / adhesives & oligomers	**Belgium**: Printed-layer NIAS prioritisation (Sciensano); **Germany**: Oligomers, evaluation challenges & method development; inks in P&B, BPA in recycled fibres.
Methods, validation & inter-lab comparability	**Belgium:** risk-based prioritisation framework for poorly characterised NIAS**. France:** emphasis on analytical capability building (advanced LC-MS), risk frameworks (TTC, QSAR), and workflows. **Greece**: Adaptation of HS-SPME-GC-MS/MS and LC-MS/MS; inter-lab comparability.

CONCLUSION — PAPER & BOARD (FCM): KEY TAKEAWAYS

9 MSs have a positive lists and/or other activities

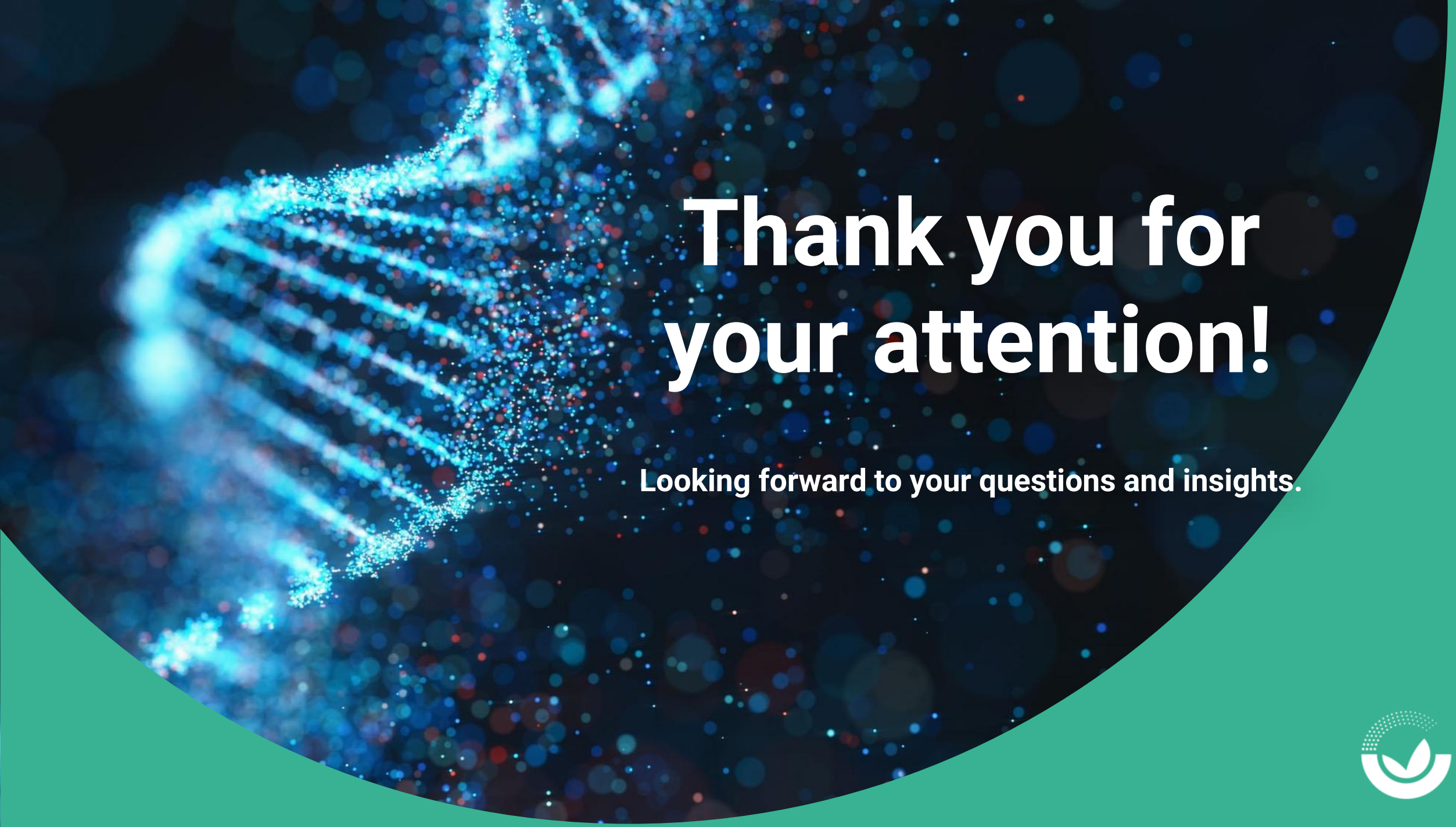
- 4 Countries with positive list(s) and safety assessment: Italy, The Netherlands, Belgium, and Germany.
- 5 Others (FR, DK, GR, NO, AT): rely on EU horizontals; invest in methods, monitoring, NIAS.

Common ground

- Safety assessment methodology follows the EFSA Note for Guidance (100%? IAS & NIAS?).

Differences

- **Positive-list design**:
  - Italy**: by substance class/function.** Two blocks: Part A (constituents), Part B (processing aids)
  - Belgium: **by substance class (single list).** fibrous raw materials, mineral fillers/pigments
  - The Netherland: **by intended use/temperature.** General P&B, warm/high-temperature uses
  - Germany (BfR XXXVI series): **by application category**. P&B for food contact (XXXVI), cooking/hot filter papers & filter layers (XXXVI/1), baking purposes (XXXVI/2), and absorber pads (XXXVI/3)
- **Migration assessment:** different criteria, BfR gave more detailed through the Network presentation



Thank you for your attention!

Looking forward to your questions and insights.