ECMA Food Safety Committee
Web-meeting 19 April 2024

Participants : Michael Avemarg (Van Genechten Packaging), Sigrid Gerold (Mayr Melnhof Packaging), Carmine Iuvone (SEDA & Co-Chair FS Com), Eliza Konecka-Matyjek (WestRock), Paolo Minichini (SEDA), Elaine Murray (WestRock), Carola Poggenpohl (Mayr Melnhof Packaging), Caroline Seguin (Mayr Melnhof Packaging), Mike Turner (ECMA MD & Co-Chair FS Com), Helena Moring Vepsalainen (Metsa Group), Jan Cardon (ECMA)

Apologized : Mathilde Gros (Graphic Packaging), Christian Schiffers (FFI)

1. Introduction and welcome.
2. Approval minutes and short follow up from the Food Safety Committee 19/02/24.
3. Update on the allergen presence in printing powders.
4. Tour de table on new specific food safety concerns and developments.
5. Legal developments.
   - Review FCM legislation.
   - BPA draft regulation.
   - POPs Regulation.
   - Council of Europe.
   - PPWR.
6. Obtained information from the FEICA and EuPIA analytical working groups following the meetings on 26/10/23 and 19/02/24.
7. Testing conditions LT @ RT. Statement and need for verification.

8. Discussion on how to approach the identified sector initiatives.
   - Generic NIAS lists.
   - Guidelines on how to test for NIAS.
   - IP protection on “ordering” platforms.
9. Preparation visit FERA (23/04).
10. Organisation and objectives next meeting in person. (18/06)
11. Miscellaneous.

1. Introduction - Welcome

ECMA anti-trust guidelines

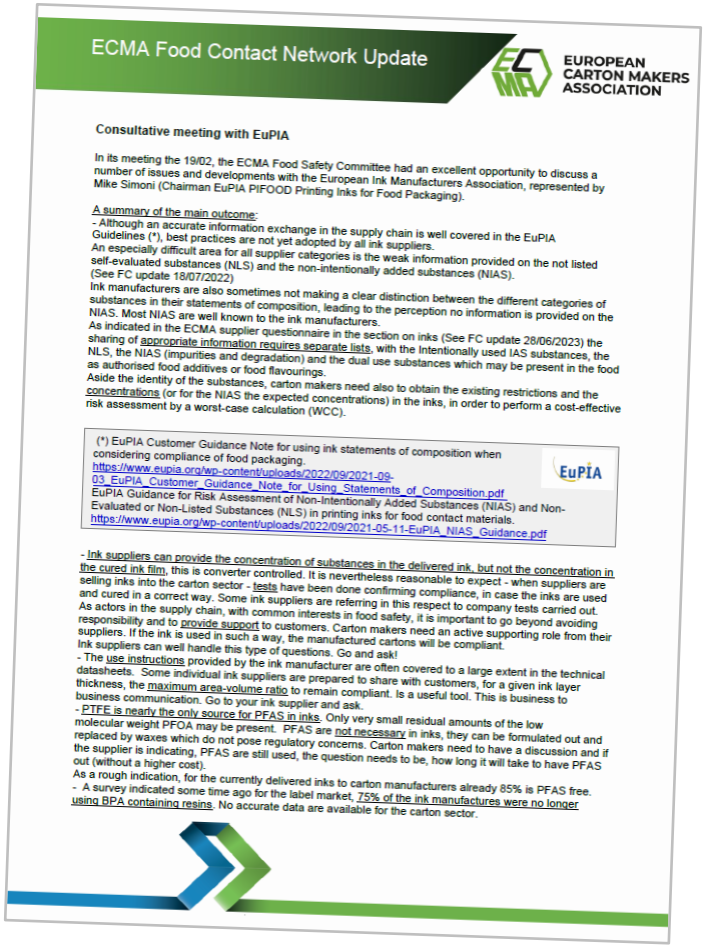
SUMMARY DO NOT

- agree in writing or in any other way on prices or pricing policy
- agree to restrict any other commercial conditions
- agree with competitors to divide territories or customers (market sharing)
- limit or control production, technical development or investment
- discriminate between customers or suppliers
- discriminate in the rules for joining or leaving a trade association
- exchange specific information with competitors on individual purchasing prices, cost price structure, sales quantities or other trading conditions
- Jointly restrict the liberty of competitors to sell and promote products at independently determined prices and conditions.
- restrict the possibilities of competitors to use a common quality label or enter into standardisation agreements with competitors that might make entry for new commerce in the market more difficult.

2. Approval minutes and short follow up from the Food Safety Committee 19/02/24.

Agenda 19/02

- Exchange with EuPIA : Information exchange,
- EuPIA Guidance documents, Testing conditions, Mineral oils in France, How to handle NIAS, UTC limits in pigments, Allergens in printing powders.
- Legal food safety developments : Review FCM legislation, BPA, Swiss Ordinance
- Statement on testing conditions



ECMA Food Contact Network Update

EUROPEAN CARTON MAKERS ASSOCIATION

Consultative meeting with EuPIA

In its meeting the 19/02, the ECMA Food Safety Committee had an excellent opportunity to discuss a number of issues and developments with the European Ink Manufacturers Association, represented by Mike Simoni (Chairman EuPIA PIFOOD Printing Inks for Food Packaging).

A summary of the main outcome:
- Although an accurate information exchange in the supply chain is well covered in the EuPIA Guidelines (*), best practices are not yet adopted by all ink suppliers.
An especially difficult area for all supplier categories is the weak information provided on the not listed self-evaluated substances (NLS) and the non-intentionally added substances (NIAS).
(See FC update 18/07/2022)
Ink manufacturers are also sometimes not making a clear distinction between the different categories of substances in their statements of composition, leading to the perception no information is provided on the NIAS. Most NIAS are well known to the ink manufacturers.
As indicated in the ECMA supplier questionnaire in the section on inks (See FC update 28/06/2023) the sharing of appropriate information requires separate lists, with the Intentionally used IAS substances, the NLS, the NIAS (impurities and degradation) and the dual use substances which may be present in the food as authorised food additives or food flavourings.
Aside the identity of the substances, carton makers need also to obtain the existing restrictions and the concentrations (or for the NIAS the expected concentrations) in the inks, in order to perform a cost-effective risk assessment by a worst-case calculation (WCC).

(*) EuPIA Customer Guidance Note for using ink statements of composition when considering compliance of food packaging.
https://www.eupia.org/wp-content/uploads/2022/09/2021-09-03_EuPIA_Customer_Guidance_Note_for_Using_Statements_of_Composition.pdf
EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials.
https://www.eupia.org/wp-content/uploads/2022/09/2021-05-11-EuPIA_NIAS_Guidance.pdf

- Ink suppliers can provide the concentration of substances in the delivered ink, but not the concentration in the cured ink film, this is converter controlled. It is nevertheless reasonable to expect - when suppliers are selling inks into the carton sector - tests have been done confirming compliance, in case the inks are used and cured in a correct way. Some ink suppliers are referring in this respect to company tests carried out.
As actors in the supply chain, with common interests in food safety, it is important to go beyond avoiding responsibility and to provide support to customers. Carton makers need an active supporting role from their suppliers. If the ink is used in such a way, the manufactured cartons will be compliant.
Ink suppliers can well handle this type of questions. Go and ask!
- The use instructions provided by the ink manufacturer are often covered to a large extent in the technical datasheets. Some individual ink suppliers are prepared to share with customers, for a given ink layer thickness, the maximum area-volume ratio to remain compliant. Is a useful tool. This is business to business communication. Go to your ink supplier and ask.
- PTFE is nearly the only source for PFAS in inks. Only very small residual amounts of the low molecular weight PFOA may be present. PFAS are not necessary in inks, they can be formulated out and replaced by waxes which do not pose regulatory concerns. Carton makers need to have a discussion and if the supplier is indicating, PFAS are still used, the question needs to be, how long it will take to have PFAS out (without a higher cost).
As a rough indication, for the currently delivered inks to carton manufacturers already 85% is PFAS free.
- A survey indicated some time ago for the label market, 75% of the ink manufactures were no longer using BPA containing resins. No accurate data are available for the carton sector.

PIJITF statement on mineral oil used in inks for packaging materials

Introduction

The members of the Packaging Ink Joint Industrial task force (PIJITF) fully support actions to mitigate the presence of mineral oil contamination used in inks for packaging materials. In the present document we touch upon ongoing analytical challenges and regulatory developments.

We exemplify this with the **French Decree 2020-1725 on Mineral Oils in Packaging**.

The above-mentioned French Decree is part of French Law 2020-105 of the 10th February 2020 on the fight against waste and promotion of the circular economy. The decree defines frameworks for waste collections and waste recovery. In its Article 112, the requirements about mineral oils used in inks for packaging materials are laid out. Art 13I and Art II target consumer health and relate to endocrine disruptor and dangerous substances respectively.

Requirements of the French Decree regarding mineral oils in packaging

The limits of mineral oils in inks to be achieved for any sort of packaging materials are defined in official Order of 13th of April 2020 which specifies the substances contained in mineral oils whose use is prohibited on packaging and in printing intended for the public.

Scope:	Oils produced from feedstocks derived from petroleum hydrocarbons used in the manufacture of inks
Substances concerned:	MOAH with 1-7 aromatic rings and MOSH with 16-35 carbon atoms
Date of entry into force:	1st January 2023

Timing:

- Until 31 December 2024: the ban on the use of mineral oils applies when the mass concentration in ink of MOAH with 1-7 aromatic rings is greater than 1%

- From 1 January 2025: the ban on the use of mineral oils applies for
  - MOAH, where the mass concentration in ink of MOAH with 1-7 aromatic rings is greater than 0.1% or the mass concentration in ink of MOAH with 3 to 7 aromatic rings is greater than one part per million (ppm)
  - MOSH with 16-35 carbon atoms, where the mass concentration in ink of these substances is greater than 0.1%

Compliance with the French Decree regarding mineral oils in packaging and analytical challenges

For Food Contact Material Applications, printing inks that do not contain mineral oil aromatic hydrocarbons (MOAH) are available on the market and should be used. This has been the position of the European Printing Ink Association EuPIA[1].

However, the PIJITF would like to highlight that the analytical possibility to accurately quantify MOAH in printed articles is still questionable. The inability to determine the source of MOAH

substances in printed articles adds another level of uncertainty. Regardless of this, the French Mineral Oil decree refers specifically to mineral oils coming from printing inks.

In addition to this, there are a number of raw materials which are allowed to be used in Food Contact Material Applications, which can easily be mistaken for mineral oils. Examples of these include paraffin waxes and the lower molecular weight fraction of polyethylene.

For these reasons it is strongly recommended that compliance with mineral oil regulations is done via a chain of custody approach where for a printing ink a discussion with the ink manufacturer, regulatory statements and a Statement of Composition are used to determine compliance.

Demonstrating compliance of the printed packaging through analytical testing is not always practical

1. Allowed substances such as paraffinic waxes covered by Plastics Regulation FCM 95 can be easily mis-identified as mineral oil. Lower molecular weight components of polyethylene waxes (polyolefin oligomeric saturated hydrocarbons – POSH) are similarly easily misidentified as mineral oil. Without a clear understanding of the raw materials used in the printed packaging as a whole it is difficult to draw the right conclusions from analytical results of mineral oils and assure compliance.

2. The French decree has in scope only mineral oil coming from printing ink. However, mineral oil components as defined by the French decree may be present in the printed packaging but originate from different sources and not from the printing ink.

When testing printed packaging it is not normally possible to determine which material in that printed packaging is the source of a specific chemical substance.

The EU Commission is working on several MOAH measures that merit attention

At a EU level, the Commission's DG SANTE is also currently working on different regulatory measures on MOAH based on the 2023 EFSA updated risk assessment of Mineral Oil Hydrocarbons in food[2]. This will include the MOAH content of white mineral oils and waxes used as food additives and food packaging materials. The EFSA has recommended in its opinion that technical specifications of white mineral oils and waxes used as food additives and food packaging materials should be updated, with detailed information about the MOAH content and composition.

We strongly recommend to take these EU initiatives and the resulting measures into account.

Swiss Ordinance : Clarifying note from authorities announced. SVI event 19/06.

3. Update on the allergen presence in printing powders.

FFI Quality Managers Committee
Minutes meeting 17/03/24

Wheat-based printing powder: The food labelling regulations for allergens stipulate that even traces of wheat must be indicated on the packaging. Wheat-based printing powder, which could be detected by any swab test, could be relevant. Alternatives could be powders based on potato starch or tapioca. An implemented allergen management (and GMO management) is essential. This means that suppliers must monitor the allergen-free status of products. At the meeting, experiences in dealing with the topic since the last meeting of the working group on 17 November 2023 were shared. Individual members pointed out that requests in this regard had also been made with regard to aids, operating materials and hygiene equipment (gloves, hairnets, beard nets, etc.).

4. Tour de table on specific food safety concerns and developments.

Notifications 15/02-17/04

European Commission | **RASFF Window**

-- Help --

SEARCH | CONSUMERS | TRACES

2024.1172	Food contact materials	food contact material	Lead, phtalates and photoiniators in pizza boxes from Spain	20 FEB 2024		France	alert notification	serious
2024.1401	Food contact materials	food contact material	Plomb and phtaltes in pizza boxes from Italia	27 FEB 2024		France	alert notification	serious
2024.1377	Food contact materials	food contact material	Lead and phtalates in pizza boxes from Italia	27 FEB 2024		France	alert notification	serious
2024.1555	Food contact materials	food contact material	Lead, phtalates, photoinitiators and BPA in pizza box from Turkey	5 MAR 2024		France	information notification for attention	serious

2024.1753	Food contact materials	food contact material	Migration of photoinitiators from packaging into sheep's cheese from Bulgaria	11 MAR 2024		 Germany	information notification for follow-up	potential risk
2024.1968	Cocoa and cocoa preparations,...	food	MOAH contamination in roasted coffee	15 MAR 2024		 France	information notification for attention	**serious**
2024.2002	Cereals and bakery products	food	Mineral oil components (MOSH/MOAH) in rice from India	15 MAR 2024		 Germany	information notification for follow-up	**potentially serious**
2024.2083	Fats and oils	food	MOAH in Palm Mid Fraction from Denmark	19 MAR 2024		 Netherlands	alert notification	**potentially serious**
2024.2707	Herbs and spices	food	MOAH and pesticide residues in Sichuan Pepper from China	5 APR 2024		 Netherlands	alert notification	**serious**
2024.2789	Ices and desserts	food	Depasire LMA Suma MOAH in prajitura /Exceeding LMA Amount MOAH in cake	9 APR 2024	---	 Romania	information notification for follow-up	**potentially serious**

2024.2843	Fats and oils	food	Wysoka zawartość MOSH i MOAH w oliwie z wytłoczyn z oliwek pochodzącej z Hiszpanii // high MOSH and MOAH content in olive pomace oil from Spain	10 APR 2024		Poland	information notification for follow-up	**potentially serious**
2024.2976	Food contact materials	food contact material	Phtalates in paper plates	12 APR 2024		France	alert notification	**serious**
2024.2988	Food contact materials	food contact material	Bisphenol A in recycling serviettes from Germany	12 APR 2024		Germany	information notification for follow-up	potential risk
2024.3103	Herbs and spices	food	Detection of mineral oil hydrocarbons in vanilla powder	17 APR 2024	---	France	information notification for follow-up	potential risk

MO in food : 7 (Germany 1, France 2, Netherlands 2, Romania 1, Poland 1)

FCM : Lead 3, Plomb 1, DEHP 3, DBP 5, DIBP 5, DINP 2, DIDP 2, 1HCPK 3, BPA 2,
Methyl-2-Benzoylbenzoate 1 (France 5, Germany 2)
Pizza boxes 4 (France), cheese ? 1, Paper plates 1, Serviettes 1

5. Legal developments.

Review EU FCM legislation

Workshop E&Y - DG SANTE 15 March

E&Y mandated to develop three policy options to support an IT infrastructure required for information exchange, verifying compliance and facilitating controls in the FCM supply chain.

FC update 5/03. Possibility to participate.

FS Com mail 13/03

ECMA input covered in Draft Report See Annex pages 80, 98 and 122 :

- In favour of a centralized digital system to exchange compliance information.

- "In principle, all actors in the chemical industry should communicate the full information on NIAS along the supply chain. However, most of the time the responsibility of compliance of the NIAS is transferred to the producer of the final product. As stated by the European Carton Makers Association, an advanced information sharing contains also information on the used self-evaluated not listed substances, the dual use substances, the NIAS and accurate use instructions. Indeed, the lack of such information makes it is difficult to perform a risk assessment at the end of the supply chain and creates obstacles for ensuring compliance of the final FCM."

Introducing the policy options

The study team was tasked with developing three policy options to support an IT infrastructure for information exchange and verification of compliance

		Governance	
		Centralized	Decentralized
IT	Centralized	Policy Option 1 A unique **EU-level** database used by all stakeholders in the FCM supply chain, and managed by an **EU entity**.	Policy Option 2A Decision-making is shared between **Member State** each of them manages their **own database,** which are connected to central database at the EU level.
	Decentralized		Policy Option 2B Decision-making is shared between **Member State** each of them manages their **own database** for the country / FCM activity they oversee, with **interoperability** between systems. Policy Option 3 Decision-making is shared between **Industries** each of them manages their **own database.**

ECMA Option 1 : offers possibility to overcome double source, confidentiality and may bring clarity for converters on what to check.

E&Y in favour of 1

Commission : 1 will not happen in favour of 3 with just a type of central access point towards the industry data and in harmonised format.

(Comment in PIJIF : confidentiality !)

→ Finalisation of the report.

Study on sustainability of food contact materials (Contractor not disclosed yet)

Define the understanding of sustainability when applied to FCMs.

Identification sustainable products already on the market or under development.

Identification policy measures that have the potential to increase the sustainability of FCM and characterise policy measures.

Next in review process :

Publication policy paper by summer. (6 pillars)
Discussion in working groups of experts per pillar to refine the policy paper.
Impact assessment.
Most of the legislative work in 2026.

BPA draft regulation ECMA Round table meeting 19/03. Circulation 2 positions10/04

EUROPEAN CARTON MAKERS ASSOCIATION

PRO CARTON
PACKAGING FOR A BETTER WORLD

Statement on the European Commission's draft regulation on the use of Bisphenol A and other bisphenols & their derivatives.

ECMA is the international network of folding carton organisations; cartonboard mills, folding carton businesses, national folding carton associations and suppliers to the carton industry.

Pro Carton is the European Association of Carton and Cartonboard manufacturers

We closely follow all developments regarding food safety issues and awareness on the concerns related to BPA have been regularly communicated with existing supplier questionnaire templates already containing specific questions on avoiding the intentional use of a number of substances of concern, including BPA.

It is premature to issue a sector position on legislative work in progress, however should the currently available version be adopted we see the folding carton and cartonboard sector's responsibility, as follows:

- Folding carton converters need to obtain from their suppliers (cartonboard, inks and varnishes, adhesives) a declaration of compliance that BPA and other bisphenols and their derivatives with a similar toxicological profile are not intentionally used.
- Based on this information from upstream in the supply chain, the folding carton maker can declare compliance towards the food product customers.

The monitoring for the presence of unintentional BPA in recycled paper and board should be carried out by the mills producing the recycled paper and board.
Given the widely used BfR Recommendation XXXVI in the paper industry, this control is already common practice in many board mills, especially for wet and fatty food contact packaging.

From a conceptual perspective, further discussion on this BPA regulation - with regard to the monitoring - might consider the use of the cartonboard containing recycled fibres.
Bisphenols are non-volatile, which means that migration only occurs in direct contact, with mainly moist and fatty foods.
Given the ban on the use of BPA, contamination levels are already falling and monitoring could be limited to only those applications where there is a risk of exposure.

9 April 2024

ECMA, the European Carton Makers Association
Contact: Mike Turner, Managing Director
Tel. +31 70 312 39 11

PRO CARTON, the European Association of Carton and Cartonboard manufacturers
Contact: Horst Bittermann, Director General
Tel. +43 664 852 74 58

Position shared with Belgian authorities.
Confirmation : Not on agenda SCoPAFF April.
Adoption in June. Monitoring may be left out.

The POPs Regulation – Possible Impact

PCB Content in supplied pigment (based on ETAD data, June 2022)

Colour	> 10ppm possible	< 10ppm	< 5 ppm	< 1ppm	Not known
Blue			PB15 PB15:1-15:6	PB76	
Brown		PBr23			
Green			PG7	PG36	
Orange	PO34	PO13	PO43	PO61	PO36
Red	PR2 PR112	PR144 PR166 PR214 PR254		PR48:4 PR202 PR220 PR221	PR5 PR170 PR184
Violet	PV23				
Yellow	PY13 PY14 PY17 PY81 PY83	PY12	PY174	PY93 PY95 PY109 PY110 PY128 PY138 PY168 PY183 PY191:1	PY1 PY3

PCB Content in supplied pigments (typical values for ETAD members only)

Key:
Top Priority = 8 CI grades where >10ppm is still possible
High Priority = 10 CI grades which fall between 1ppm and 10ppm
Important = 4 Other Important CIs that are < 1ppm
Others in Bold are also important but of unknown PCB content (no data available from ETAD)

5

Outcome meeting with Commission 15/03

Bilateral individual meetings with pigment suppliers, to discuss what is feasible.
0,1 ppm is off the desk. 25 ppm, 10 ppm within 3 years …

COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

COUNCIL OF EUROPE

European Directorate for the Quality of Medicines & HealthCare

EDQM 60 1964 - 2024

STAKEHOLDER CONSULTATION

Draft technical guide on documentation supporting compliance and safety of food contact materials and articles

To participate in the consultation, please download the draft technical guide and the designated comment form. Complete the designated comment form with your input, in English or French, and send it to the specified e-mail address by **30 April 2024 at the latest**.

Please note: comments submitted in any other file format or after the deadline will not be taken into account.

Stakeholder consultation – New draft technical guide on FCM compliance - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)

Department of Biological Standardisation,
OMCL Network and HealthCare (DBO)
-Consumer Health-

European Committee for Food Contact Materials and Articles (Partial Agreement) (CD-P-MCA)

EDQM 60 1964 - 2024 COUNCIL OF EUROPE 75 1949 - 2024 CONSEIL DE L'EUROPE

Technical Guide – Documentation supporting compliance and safety of food contact materials and articles

Draft for consultation

EDQM CONSULTATION FORM

Enter your comments exclusively in this excel file using the line numbers in the consultation text. Save the completed form (as an excel file) and send to **fcm.consultation@edqm.eu as an email attachment** by 30 April 2024. **Consultation closure: 30 April 2024**. Comments submitted in any other file format or beyond this deadline will not be treated.

Data and comments submitted below may be disclosed to mandated reviewers. Personal data will be kept for 2 years maximum by the EDQM. Responses submitted without name, email or affiliation details will be treated anonymously.

**Language of submitted comments (select EN/FR with dropdown)*	EN
**Email use consent (select YES or NO)*	YES *With my email submission, I hereby consent to the storage and use of the given email address to receive related information on the same topic, where applicable.*
Email address (optional)	jan.cardon@ecmabel.be
Name (optional)	Jan Cardon
Affiliation (optional)	*ECMA European Carton Makers Association (Comments adopted in the ECMA Food Safety Committee meeting 19/04)*
Country (optional)	*Belgium*

CONFIDENTIAL

COMMENT ENTRY

First select the corresponding **Section range** line numbers from the dropdown list. The corresponding chapter/section *appears automatically* in the next column **Section**. In the following column (col C), type the beginning **Line number concerned by your comment** found in the consultation text. Next, select **Comment type** (dropdown list col D).

To type or paste your comment or text, **double-click in the cell in column (E) Comment or in column (F) Suggested text**. Please note that you will not be able to save any comment if you do not first select the relative Section range in col A and First line in col C. Please complete only one comment/suggested text per row.

Section range* *select lines from list*	Section *appears automatically*	First line* concerned by comment *type line number*	Comment type *(optional) select from list*	Comment on the text *enter your text*	Suggested text *enter your text*

3-39	1. Introduction	22	Other	Support for the wording in the lines 22-26. Compliance of final FCM is a shared responsibility and the compliance work needs to be completed at the earliest stage. The detailed knowledge on the substances is with the chemical suppliers upstream.	
3-39	1. Introduction	38	Other	Support for the "shared responibility" wording in lines 38-39.	
41-56		54	Other	The obligation to provide all relevant information in DOCs expressed in the used verb "must" is welcomed.	
88-91		88	Other	The possibility to develop documentation at the product family level is welcomed.	
92-106		98	Other	Valuable to address both, storage conditions before and during food contact. Lines 98-103.	
107-119	3.4 Starting materials	107	Other	This section is clearly stating what is expected from the suppliers of starting materials. Impurities, stability ... maximum use level ... reaction products to be expected.	
120-127	Table 1. Substances used per supplier	120	Other	All impurities and reaction products need to be included in the tables, from where information is shared in the DOC.	
153-164	3.8 Reactions potentially at later stages of the manufacturing chain	153	Other	It is indeed essential, the reactions potentially occuring later in the supply chain are taken in account. If not the supplier can not make a correct assessment on what he needs to share in the DOC.	

174-182	3.10 Maximum migration to be expected	174	Other	Valuable to require clarity on the maximum migration to be expected and on mg/kg or mg/dm²	
198-208	3.12 Restrictions	203	Other	Valuable, the double source problem is covered.	
226-231	3.15 Relevance of functional barrier	226	Other	Clarity on the barrier effcetiveness is indeed essential for the Risk Assessment.	
120-127	Table 1. Substances used per supplier	120	Technical	In a first reading the technical guide may be somehow confusing: tabel 1, tables 2A and 2B and DOC's. Why not including an additional figure similar to figure 1, well visualising the tables are part of the supporting documentation for inhouse use and towards the enforcement authorities, allowing the development of appropriate DOCs.	
92-106	3.3 Intended use and restrictions	104	Technical	v. contact surface area per amount of food for which compliance needs to be shown;	v. maximum contact surface area and amount of FCM (e.g. film thickness) per amount of food for which compliance needs to be shown;
198-208	3.12 Restrictions	201	Editorial	Assume 201/202 are mixed up with 206/208.	
209-221	3.13 Compliance work downstream	220	Technical	The wording in lines 220-221 may be understood as an open door for broad disclaimers.	Proposal to skip.

PPWR

Plastics Regulation Amendment 18

Keller & Heckman

The European Commission (EC) announcement of the draft amendment indicates that the Regulation aims to increase quality control under the Plastics Regulation by: (1) ensuring alignment with other regulations, (2) introducing purity requirements for substances obtained from waste and natural materials; and (3) adapting migration testing of multi-layer materials and repeat testing.

MMML testing for OML & SML.
Testing conditions …
Consultation was open until the 15/04.

PFAS

Restriction proposal 5 Member States reviewed.

6. Obtained information from the FEICA and EuPIA analytical working groups following the meetings on 26/10 and 19/12.

FEICA reply 11/04

We propose testing 10 days at 40 degrees.

This method is used today by laboratories already and the choice can be justified as follows:

1) Choice of simulant: In paper and cardboard packaging for dry foods, migration of adhesive ingredients into foodstuff is largely confined to gas phase (vapour phase) transmission. This migration pathway is adequately simulated using Tenax® as a food simulant.

2) Acceleration of Migration: Elevated temperatures can accelerate the migration of substances from the packaging material into the food product. By testing at 40 degrees Celsius, which is higher than typical room temperature, the migration process is accelerated, allowing for a shorter testing period while still capturing potential migration behaviour over time.

3) Duration of 10 days: experience shows that after 10 days there is not much migration anymore.

However, if you want to be sure what is the exact migration, the test will have to be done in the food, ideally under the temperature and storage conditions as expected.

Again, to our knowledge the laboratories are used to working with this procedure. If you encounter any other comments, we would be interested in hearing about it.

EuPIA Draft white book shared (11/04)

Allowed to add Fraunhofer in own statement.
Offer to arrange an online discussion with their analytical expert team.

Table 1: Overview of representative surrogates for printing ink components

Surrogate	Molecular Weight (g/mol)	Log $P_{o/w}$
Irgacure 184 (CAS 947-19-3)	204.3	2.34
Di-tert-butylhydroxytoluene BHT (CAS 128-37-0)	220.4	5.32
Irganox 1076 (CAS 2082-79-3)	530.9	13.9
2,4,7,9-Tetramethyl-5-decin-4,7-diol (TMDDO) (CAS 126-863)	226.4	3.11
Hexadecane (C16) (CAS554-76-3)	226.6	9.26
Octadecane (C18) (CAS 593-45-3)	254.5	10.3
Eicosane (C20) (CAS 122-95-8)	282.5	11.4
Docosane (C22) (CAS 629-97-0)	310.6	12.4
Tetracosane (C24) (CAS 646-31-1)	338.7	13.5
The following surrogates are removed from the overall data set due to experimental inconsistences cited in the original report:		
Di(trimethylolpropane)tetraacrylate (DiTMPTA) (CAS 94108-97-1)	466.5	4.26
2-Phenoxyethyl acrylate (CAS 48145-04-6)	192.2	2.71
Acetyltributylcitrate ATBC (CAS 77-90-7)	402.5	6.92
2-Ethylhexanol (CAS 104-76-7)	130.2	2.82
Erucamide ESA (CAS 112-84-5)	337.6	8.87
Dodecane (CAS 112-40-3)	170.3	7.13
Benzophenone (CAS 119-61-9)	182.2	3.18
2-Methylpropane (CAS 2163-42-0)	90.1	0.24

3.2.2. Cardboard 240 g/m²

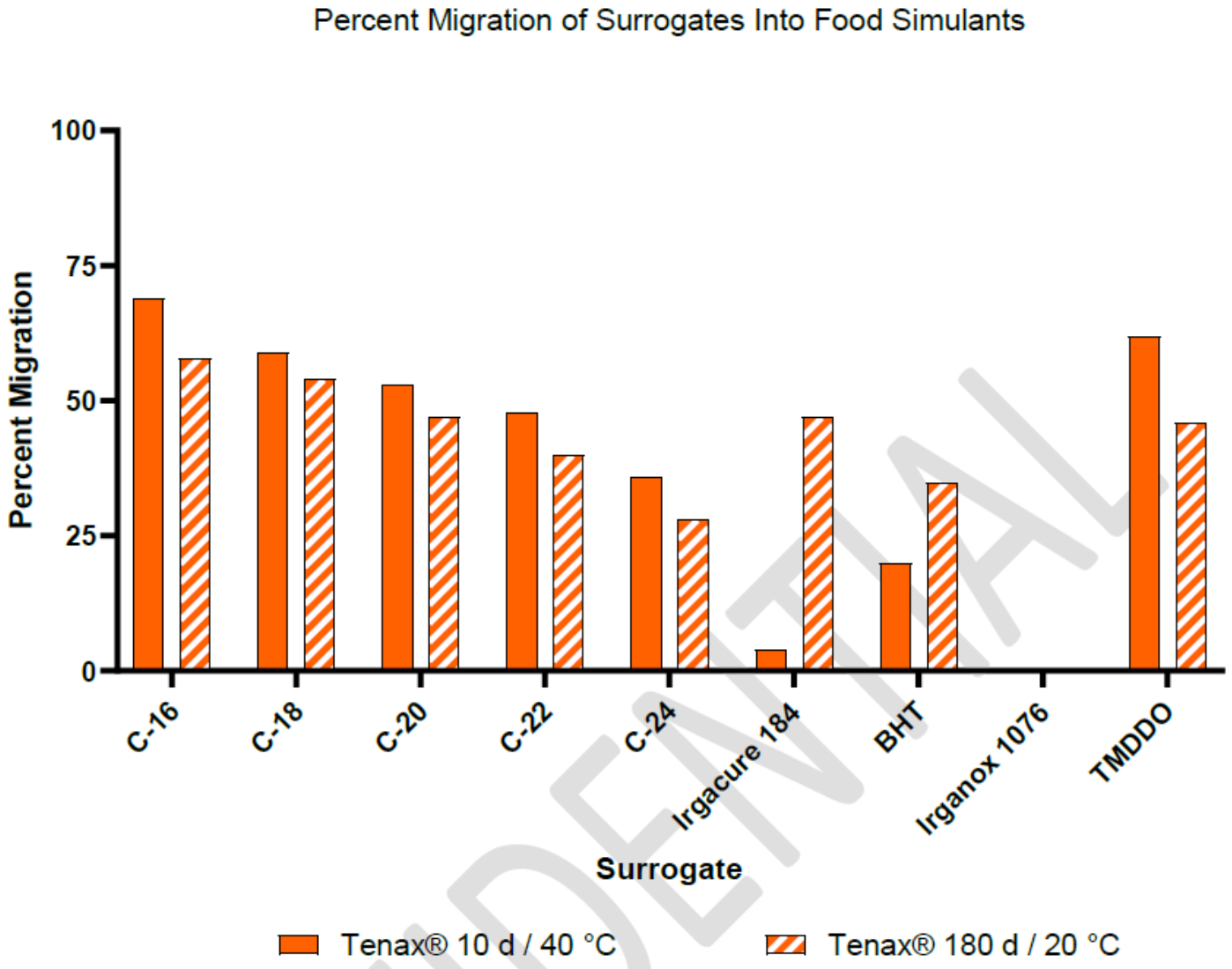


Figure 4: Tenax® migration from printed cardboard at 10 d / 40 °C and 180 d / 20 °C

4.2. Cardboard (all surrogates)

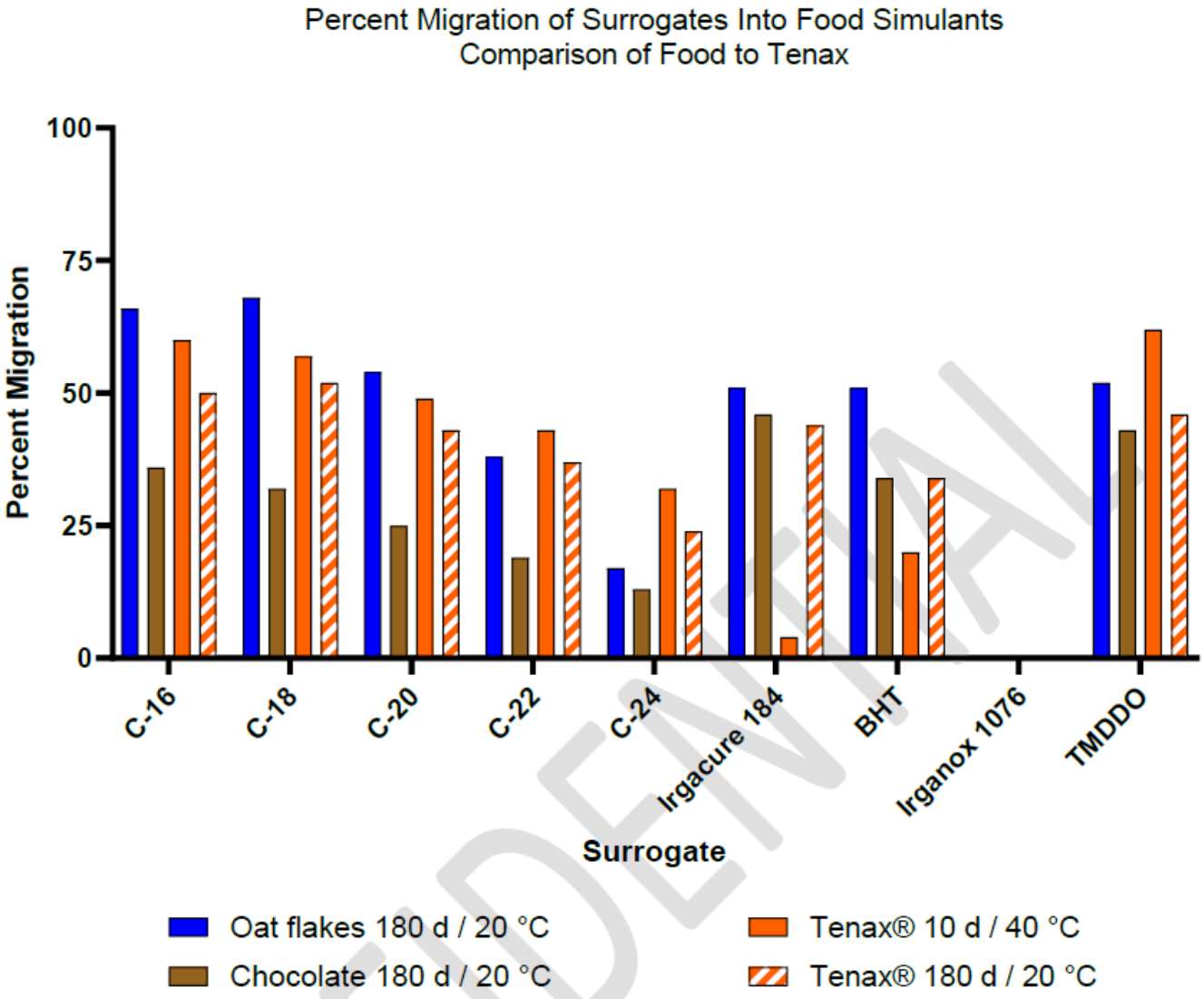


Figure 7: Comparison of migration for all surrogates from printed cardboard onto Tenax®, oat flakes and chocolate under defined test conditions

In conclusion :

In the case of printed board, Tenax migraton 10 days at 40 °C just covers food migration, but not to the extent desired, e.g. 2-3 fold. Testing migration at 40 °C for incubation durations above 10 days, as suggested in the DIN SPEC 5010:2018-05 [2], could be a valid approach in this case. Further studies in this regard would be useful.

DIN SPEC 5010

Testing of paper and board — Determination of the transfer of mineral oil hydrocarbons from food contact materials manufactured with portions of recycled pulp

8 Test conditions

8.1 General

The test conditions for storage with MPPO are specified in Table 1.

Table 1 — Test conditions for the storage with MPPO

Time days	Temperature °C	Evaluation of storage at ambient temperature
10	40	up to 12 months
30	40	up to 24 months

NOTE 1 The conditions specified in Table 1 are based on kinetic comparative studies between migration testing with MPPO and real storage conditions.

NOTE 2 Test temperatures above 40 °C for further acceleration of the method have proved to be unsuitable.

7. Testing conditions LT @ RT.

ECMA STATEMENT ON TESTING CONDITIONS

April 2024

This statement reviews ways to test the migration of cartons stored for a long term (> 6 months) at room temperature.
In recent months, this topic, has been discussed at length within the ECMA Food Safety Committee and with the various experts from European associations representing the materials used by carton makers, including FEICA (Adhesives and Sealants Industry), EuPIA (Printing Ink Association) and CEPI (Confederation of Paper Industries) and, has also been raised with the Joint Research Centre, the Belgian public research institute Sciensano and in the Packaging Ink Joint Industry Task Force.

Appropriate testing, among other means of assessing compliance, is part of the process flow of producing food-safe cartons.
As described in early ECMA GMP documents, this testing can be efficiently performed for so-called packaging systems, combinations of a well-defined substrate, ink and adhesive for a particular type of application. Once such a specific combination has been thoroughly tested, the packaging system can be used safely for many customers.

The Plastics Regulation (EU) No 10/2011 does not apply to paper and cardboard packaging, but in view of the misconception among some customers and laboratories that cartons should anyway be tested according to the approaches for plastics, the existing publications of the authorities and the guidelines of industry associations were carefully reviewed.
The level of safety should be the same for all packaging materials, although the material's intended use, properties and migration behaviour may differ greatly.
For the vast majority of cartons with no plastic barrier coating, tests with liquid simulants are for instance not representative of migration from cartons.

In principle, testing migration into the packed food itself prevails, but if a simulant is used, modified polyphenylene oxide (MPPO) is suitable for assessing migration from cartons.
A recently developed alternative method is testing into infant powder, which is used as a kind of worst-case highly migration-sensitive type of food.

Which conditions to use?
Based on the Plastics Regulation, as indicated, some customers tend to require for long-term storage at room temperature, testing for 10 days at 60°C.
Apart from the fact that this legislation is not applicable, those conditions are also not representative of the effective use of cartons. As specified in Annex V "Compliance Testing" of the Plastics Regulation, such test conditions "cover storage for more than 6 months at room temperature and below, including hot filling and/or heating up to 70-100°C for - varying with the temperature - 15 minutes (100 °C) to 2 hours (70°C)."
These higher temperature conditions (associated with, for example, the pasteurisation process and hot filling), do not occur in the processing of regular cartons.

As no specific harmonised EU legislation exists for paper and board articles, the only material specific authorities' reference is the Council of Europe Resolution CM/Res (2020) 9, and the Technical Guide on paper and board used in food contact materials and articles. [1]
In the section on "Conditions of testing" it is stated "The worst foreseeable conditions of contact of the test specimen (paper or board material or article) with food are to be chosen for testing".
The Council of Europe publication refers (out of the scope of this note) for contact with liquid foods or beverages to the JRC publication "Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware)" and provides guidance on the testing conditions for baking and microwave oven applications.

Aside the review of those official references the ECMA Food Safety Committee has had discussions and exchanges with leading food safety experts from the European associations representing the suppliers of the FCM materials, carton makers are using and with experts involved in the Packaging Ink Joint Industry Taskforce.

In a meeting with FEICA, their publication "Migration testing of adhesives intended for food contact materials" (Version 10/05/2023) was discussed [2] and the section "Accelerated tests at elevated temperature" states, "for certain types of adhesive applications, a change of physical properties will take place at temperatures of 60 °C. The observed migration will in such cases be substantially different from the real long-term migration at room temperature or even at 40 °C. In these cases, the migration results obtained may not be valid."

This same observation related to the physical and chemical changes which may happen to the migrating compounds was also part of the discussion with EuPIA and is well covered in the "EuPIA Guidance on migration test methods for the evaluation of substances in printing inks and varnishes for food contact materials. (Version 03/05/2023)". [3]
The EuPIA publication contains in the section "Selecting migration parameters" a table with testing conditions based on the difference between dry and liquid/moist food, the contact time and the food contact temperature. For dry foods used below 40 °C, this table is indicating MPPO testing at 40 °C. for 10 days. Based on a recent EuPIA migration study conducted at Fraunhofer IVV, it has however been stated by experts from the ink industry, it may be appropriate to prolong the testing time to 30 days to compensate the lower testing temperature.

In fact, the derogation of testing at a lower temperature is also well included in the Plastics Regulation itself.
Annex V paragraph 2.1.3 (i) contains the wording: "If it is found that carrying out the tests under the combination of contact conditions specified in the tables causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place."

Based on these various publications and discussions, ECMA assumes that it is appropriate to perform compliance tests for regular cartons stored for a long term (> 6 months) at room temperature, at 40 °C. In accelerated tests a pragmatic approach may be, to test at this temperature for 30 days unless there is scientific evidence that the migration of the present substances reaches equilibration at a different testing time.

Approval statement. Need for verification ? Existing company data ?

8. Discussion on how to approach the identified sector initiatives.

Generic NIAS lists.

Guidelines on how to test NIAS.

IP protection on “ordering” platforms.

9. Preparation visit FERA (23/04)

Participants : Mathilde Gros, Eliza Konecka-Matyjek, Elaine Murray, Annika Schrimpf, Caroline Seguin, Jan Cardon

So far announced topics :

- Introduction ECMA and FERA.
- Presentation of the laboratory and the areas of expertise.
- Update on the main legal food safety developments in the UK. Identified differences with EU legislation ? US ?
- FERA approach to the upcoming changes in EU legislation : very low LOD for BPA and other bisphenols, very low levels of impurities (plastics regulation) … Are the migration labs prepared for those changes?
- Exchange on the typical substances in focus : PFAS, bisphenols, MO, phthalates, ED ... FERA’s view on specific substances to monitor. How is FERA presenting its test results in reports? Detail or just pass/fail?

- Confidentiality in supply chains and on third party portals. Work for sector associations ?
- Discussion on how to assess the safety of finished cartons.
  Declarations from suppliers, analytical testing, bio assays, modelling, …
  Appropriate testing conditions. LT @ RT …
- NIAS assessment.
  General knowledge available at FERA on typical NIAS which may appear in carton board (virgin & recycled), sheet inks & varnishes, hotmelt and waterbased adhesives …
  How to exclude genotoxicity ?
  Bioassays and HPTLC.
  Accessible databases for mass spectra.
- How to handle food contamination in paper for recycling.

+ Visit facility and equipment

10. Organisation and objectives next meeting in person. (18/06)

- Review ECMA documents.
- Bio Detection Systems ?

11. Miscellaneous

Thank you for your attendance and contributions !