# ECMA Food Safety Committee
# Web-meeting 19 February 2024

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

Guest : Mike Simoni (Chair EuPIA PIFOOD Committee)

Apologized : Carmine Iuvone (SEDA & Co-Chair FS Com)

**Suggested agenda :**

1. Introduction and welcome.

2. Exchange with EuPIA.
   Mike Simoni, Chair of the EuPIA PIFood Committee (Printing Inks for Food Packaging) is joining.

   - Information exchange between ink manufacturers and carton makers.
   - Specific questions related to the EuPIA Guidance documents.
   - Testing conditions LT @ RT.
   - Mineral oil requirements in France.
   - How to handle the NIAS.
   - UTC limits in pigments.
   - Allergens in printing powders.
   - PFAS /BPA

3. Approval minutes and short follow up from the Food Safety Committee 13/12/23.
4. Tour de table on specific food safety concerns and developments.
5. Legal food safety developments.
6. ECMA statement on testing conditions.
   - Obtained additional information.
   - Draft statement.
   - Expert involvement.
7. Update sustainability related topics.
8. 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. Exchange with EuPIA.

Mike Simoni, Chair of the EuPIA PIFood Committee (Printing Inks for Food Packaging) is joining.

## 1 Information exchange between ink manufacturers and carton makers.

Member survey

**INFORMATION EXCHANGE IN THE SUPPLY CHAIN - STATUS 03/ 2022**

For an assessment of the safety of food packaging it is essential to obtain accurate information from suppliers of inks, varnishes, adhesives, cardboard.
The objective of this questionnaire was to identify the remaining weaknesses in the current information flow.

The questionnaire was addressed to all companies involved in the Food Contact e-mail network of ECMA. Replies were obtained representing in total carton manufacturing in 52 production sites.

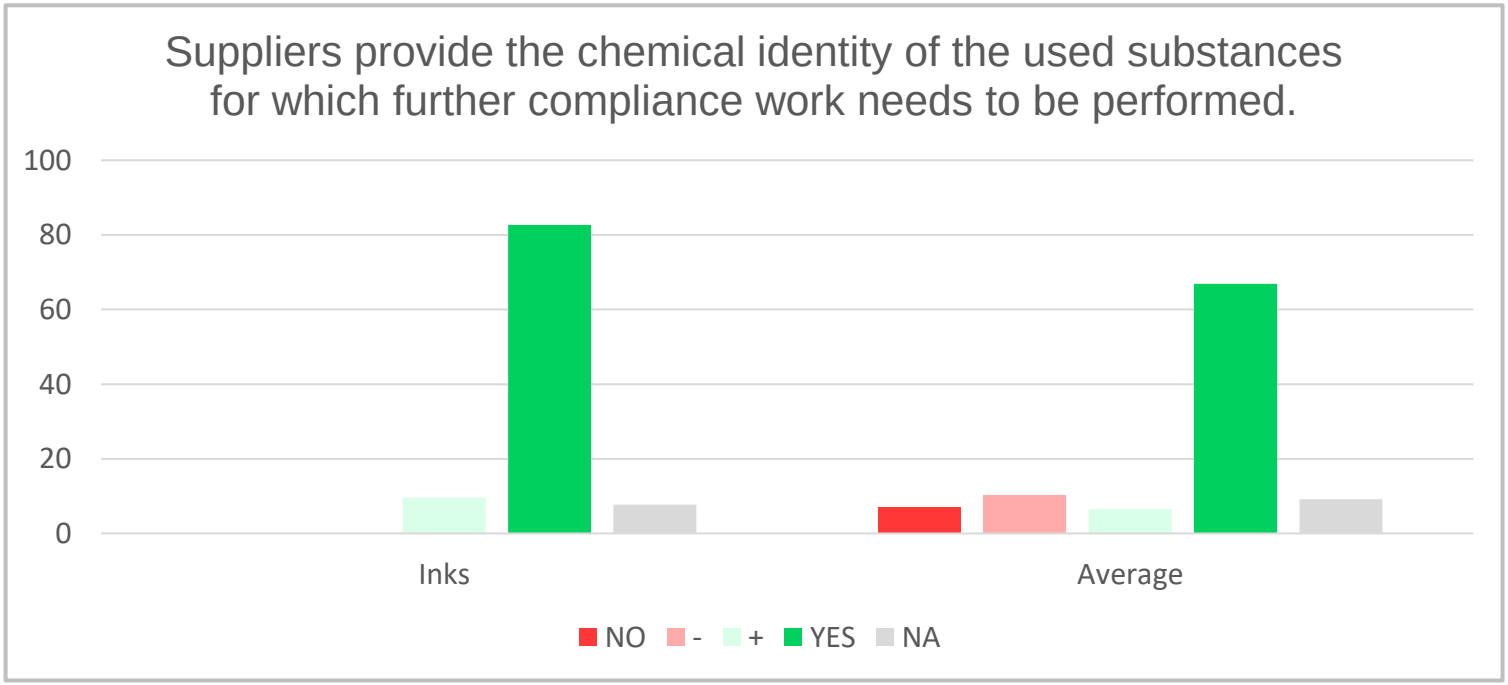
Per item in the questionnaire, 4 scoring options were possible : NO (no important supplier fulfils), predominantly NO "-", predominantly YES "+", and YES (all important suppliers fulfil).
In case no answer was provided for a certain question, the reply is included in the "NA" column (no answer/not availbale).
Often the "NA" column can be assimilated with the "NO" replies.
The questions considered as essential are presented in black, while those in grey are related to a more advanced information exchange.

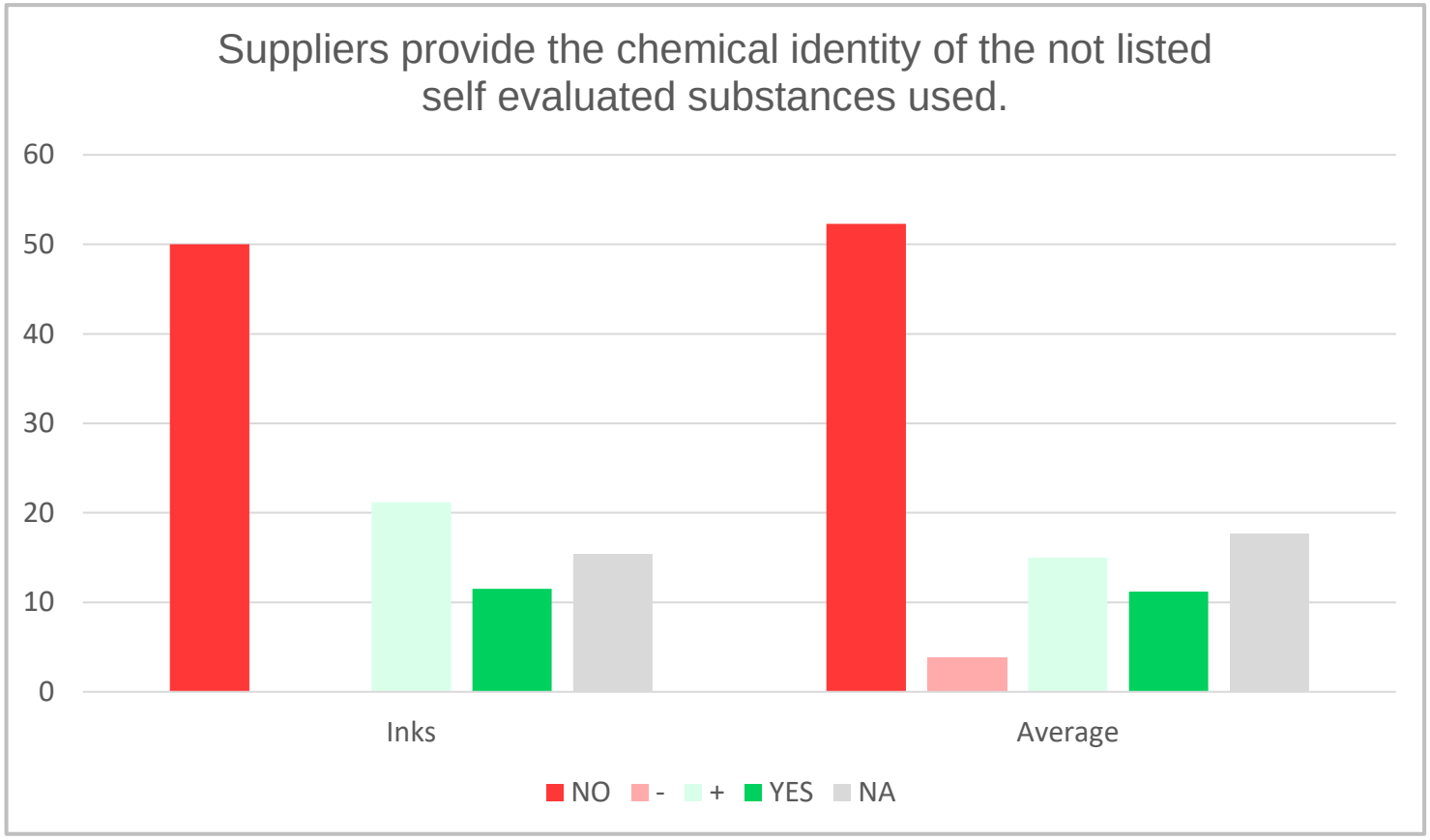
| From your 3 or 5 most important suppliers per FCM catergory for the manufacturing of **food cartons** you obtain | INKS (1) | | | | | AVERAGE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **NO** | **-** | **+** | **YES** | **NA** | **NO** | **-** | **+** | **YES** | **NA** |
| **a confirmation of compliance with** | | | | | | | | | | |
| the Food Contact Framework Regulation 1935/2004 (in case the use instructions are respected and good production parctices are applied) and the GMP Regulation 2023/2006. | 0,0 | 1,9 | 1,9 | 90,4 | 5,8 | 0,8 | 1,9 | 5,0 | 86,5 | 5,8 |
| reference legislations : Swiss ink ordinance (1&2) - Plastics Regulation (3) - BfR 36 (4&5) … | 1,9 | 0,0 | 19,2 | 71,2 | 7,7 | 1,5 | 0,4 | 20,0 | 69,2 | 8,8 |
| sector specific guidance : EuPIA GMP (1&2), FEICA Guidance for Food contact status declaration (3), CEPI/CITPA Food Contact Guidelines (4&5) | 0,0 | 0,0 | 1,9 | 84,6 | 13,5 | 0,8 | 6,9 | 6,5 | 70,4 | 15,4 |
| a quality management system (ISO 9001) | 0,0 | 0,0 | 9,6 | 84,6 | 5,8 | 0,4 | 0,0 | 8,8 | 85,0 | 5,8 |
| a GFSI cerification scheme (BRCGS, FSSC 22000, IFS Packsecure) | 15,4 | 17,3 | 23,1 | 34,6 | 9,6 | 9,2 | 29,2 | 15,4 | 36,5 | 9,6 |
| environmental standards (ISO 14001) | 0,0 | 17,3 | 30,8 | 42,3 | 9,6 | 0,8 | 8,1 | 31,2 | 49,6 | 10,4 |
| ethical codes (SEDEX, SMETA) | 21,2 | 3,8 | 15,4 | 17,3 | 42,3 | 13,8 | 4,6 | 24,6 | 16,2 | 40,8 |

## Intentionally added substances

| | INKS (1) | | | | | AVERAGE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **NO** | **-** | **+** | **YES** | **NA** | **NO** | **-** | **+** | **YES** | **NA** |
| **the confirmation all intentionally added substances are present** on positive lists of national regulations and recommendations, the Union List of 10/2011 or have been evaluated by an official authority (EFSA,BfR …) | 0,0 | 17,3 | 3,8 | 73,1 | 5,8 | 3,8 | 15,7 | 7,7 | 67,4 | 5,4 |
| **the chemical identity of the used substances** with specific migration limits, rsidual content restrictions or other limitations (National legislation, Union list or evaluation by an official authority) and **for which further compliance work needs to be performed by the downstream user** | | | | | | | | | | |
| Substance name and CAS number | 0,0 | 0,0 | 9,6 | 82,7 | 7,7 | 6,9 | 10,4 | 6,5 | 66,9 | 9,2 |
| Applicable restriction | 0,0 | 0,0 | 3,8 | 78,8 | 17,3 | 6,2 | 6,9 | 2,7 | 67,7 | 16,5 |
| Reference | 0,0 | 0,0 | 5,8 | 76,9 | 17,3 | 6,2 | 6,9 | 3,5 | 66,9 | 16,5 |
| Concentration in the delivered material | 19,2 | 0,0 | 11,5 | 53,8 | 15,4 | 23,8 | 1,2 | 8,1 | 51,9 | 15,0 |

| | INKS (1) | | | | | AVERAGE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | NO | - | + | YES | NA | NO | - | + | YES | NA |
| **the chemical identity of all used substances** with specific migration limits, rsidual content restrictions or other limitations (National legislation, Union list or evaluation by an official authority) | | | | | | | | | | |
| Substance name and CAS number | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 3,1 | 0,0 | 4,6 | 92,3 |
| Applicable restriction | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Reference | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Concentration in the delivered material | 0,0 | 0,0 | 7,7 | 0,0 | 92,3 | 3,1 | 0,0 | 4,6 | 0,0 | 92,3 |
| **the chemical identity of the not listed self evaluated substances used** | | | | | | | | | | |
| Substance name and CAS number | 50,0 | 0,0 | 21,2 | 11,5 | 17,3 | 52,3 | 3,8 | 15,0 | 11,2 | 17,7 |






EUROPEAN CARTON MAKERS ASSOCIATION

Supplier Questionnaire - Latest version June 2023

**Questionnaire for suppliers**

## Inks and varnishes

**General information**

Name and address of the manufacturing plant :

Trade name / reference of the supplied ink :

Type of printing ink according to the EuPIA classification : Conventional sheet-fed offset FCM ink, Oil based FCM varnish, UV-curing FCM ink or lacquer, Water-based FCM coating, appropriate inks for a direct physical touching contact (DFC inks). See updated "ECMA Statement on Direct Food Contact Inks" (June 2023) (www.ecma.org).

**Harmonised FCM legislation and ink specific regulations and guidance.**

The supplier certifies that the provided ink

**(1)** allows the converter - if used as recommended - to comply with the requirements set out in the Food Contact Framework Regulation (EC) No 1935/2004.

**(2)** is manufactured in accordance with the requirements set out in Regulation (EC) No 2023/2006.

**(3)** is compliant with the Council of Europe Resolution CM/Res (2020)9 on the safety and quality of materials and articles for contact with food.

**(4)** complies with other specified legislations. (German Printing Ink Ordianance November 2021, Swiss Ordinance 817.023.21, French AGEC law No 2020-105 and the French Mineral Oil Order May 2022)

**(5)** is manufactured in accordance with the EuPIA Good Manufacturing Practice (GMP) Printing inks for Food Contact Materials. (4th Version March 2016)

**Required adequate information**

In view of compliance with Article 3 of the Food Contact Framework Regulation, all substances (IAS and NIAS) potentially migrating from the food contact materials and articles need to be risk assessed and/or risk managed.

**The supplier needs in the statement of composition (SoC) to**

**(1)** confirm that all monomers and additives, aids to polymerization (including but not limited to UV photo-initiators), polymerization production aids, solvents, colorants and other substances added are present on, the Union list of the Plastics Regulation No 10/2011 or on positive lists in applicable national legislations and recommendations in EU Member States (or Switzerland) or have been evaluated by an official authority (EFSA, BfR …).

Chemical identity of the used substances with specific migration limits, residual content restrictions or other limitations (EU, national legislation or evaluation by an official authority) and for which - in view of compliance of the concerned material - further compliance work needs to be performed by the downstream user :

| Substance name | CAS No | Applicable restriction | Reference | Concentration in ink |
|---|---|---|---|---|
| | | | | |

Chemical identity of the used substances with specific migration limits, residual content restrictions or other limitations (EU, national legislation or evaluation by an official authority) :

| Substance name | CAS No | Applicable restriction | Reference | Concentration in ink |
|---|---|---|---|---|
| | | | | |

In case not listed self evaluated substances are used, the supplier needs to provide the identity of the substances and share details on the risk assessment and self derived restrictions.

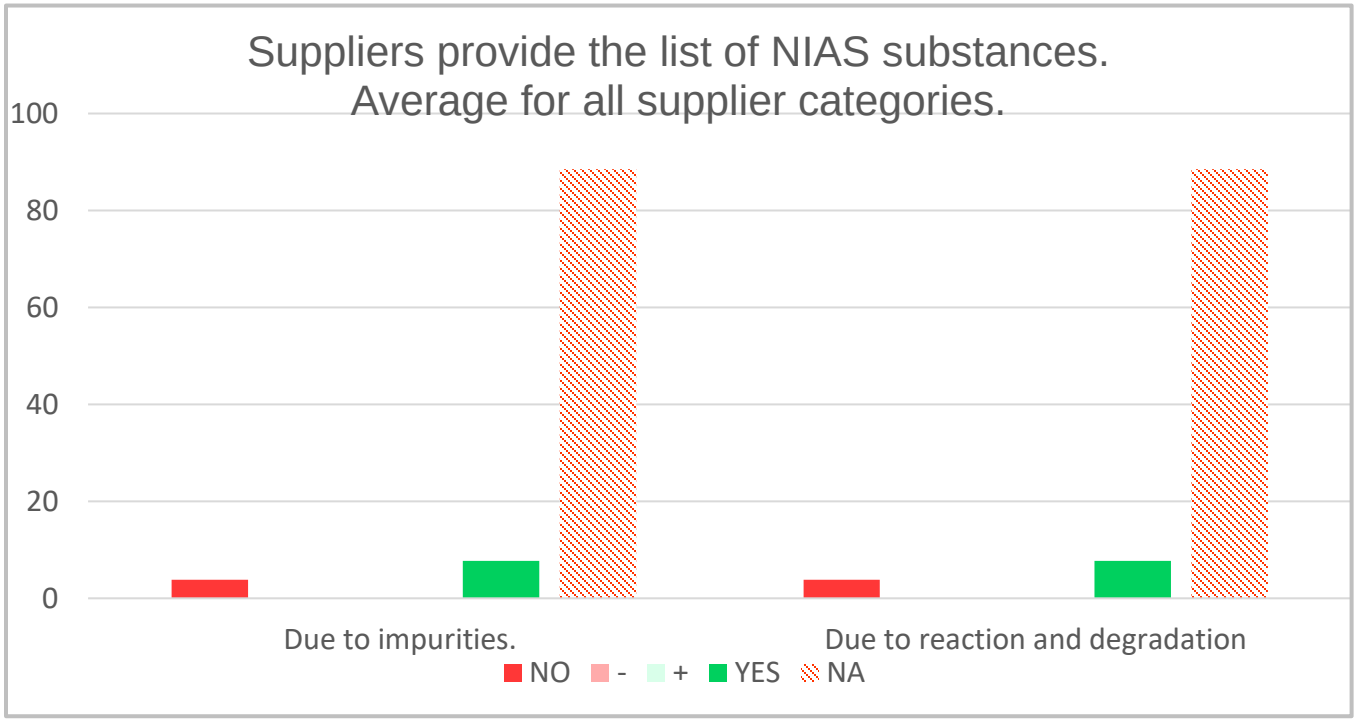
| Substance name (non listed) | CAS No | Self derived restriction | Applied RA method | Concentration in ink |
|---|---|---|---|---|
| | | | | |

In case the ink supplier considers certain information regarding the composition as confidential, a non-disclosure agreement can be drawn up.

# NIAS

Member survey

| From your 3 or 5 most important suppliers per FCM catergory for the manufacturing of **food cartons** you obtain | INKS (1) | | | | | AVERAGE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | NO | - | + | YES | NA | NO | - | + | YES | NA |
| **the confirmation the used raw materials and components meet the suitable purity restrictions**, with an indication how the impurities and other **non intentionally added substances** (reaction and degradation products) are taken into consideration in view of compliance with Article 3 of the FCFR. | | | | | | | | | | |
| Confirmation | 19,2 | 0,0 | 21,2 | 44,2 | 15,4 | 20,0 | 3,5 | 17,7 | 44,2 | 14,6 |
| Qualitative description of measures taken | 21,2 | 0,0 | 17,3 | 9,6 | 51,9 | 21,2 | 4,2 | 13,8 | 9,6 | 51,2 |
| Data, testresults | 21,2 | 7,7 | 17,3 | 1,9 | 51,9 | 21,7 | 11,2 | 14,4 | 2,0 | 50,8 |
| **the list of impurities which may be related to the used raw materials and components** | | | | | | | | | | |
| NIAS substances due to impurities . Name and CAS number. | 3,8 | 0,0 | 0,0 | 7,7 | 88,5 | 3,8 | 0,0 | 0,0 | 7,7 | 88,5 |
| Applicable restriction | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Reference | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Expected max contamination / concentration. | 0,0 | 0,0 | 7,7 | 0,0 | 92,3 | 0,0 | 0,0 | 7,7 | 0,0 | 92,3 |
| based on the chemical knowledge of the supplier and the known standard manufacturing process in a carton manufacturing plant, **the substances which may appear as reaction or degradation products.** | | | | | | | | | | |
| NIAS substances due to reaction and degradation. Name and CAS number. | 3,8 | 0,0 | 0,0 | 7,7 | 88,5 | 3,8 | 0,0 | 0,0 | 7,7 | 88,5 |
| Applicable restriction | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Reference | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 | 0,0 | 0,0 | 0,0 | 7,7 | 92,3 |
| Expected max contamination / concentration. | 0,0 | 0,0 | 7,7 | 0,0 | 92,3 | 0,0 | 0,0 | 7,7 | 0,0 | 92,3 |




## Supplier Questionnaire - Latest version June 2023

**(2)** provide the list of used substances which are also authorised as direct food additives or as food flavourings. (Dual use additives)

| Substance name (dual use) | CAS No | Applicable restriction | Concentration in ink |
|---|---|---|---|
| | | | |

**(3)** confirm the used components meet the suitable purity restrictions and indicate how the impurities and other non intentionally added substances (reaction and degradation products) are taken into consideration in view of compliance with Article 3 of the FCFR.

Based on the chemical knowledge of the supplier, which impurities may be related to the used raw materials and components by the ink manufacturer ? Which substances may appear as reaction or degradation products and need to be taken in account in view of compliance with Article 3 of the FCFR ?

| NIAS Substances | CAS No | Applicable restriction | Reference | Expected max. contamination / concentration |
|---|---|---|---|---|
| | | | | |
| | | | | |



**Discussion**

# Use instructions

Member survey

| | INKS (1) | | | | | AVERAGE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | NO | - | + | YES | NA | NO | - | + | YES | NA |
| **detailed use instructions** | | | | | | | | | | |
| Suitability for food contact | 1,9 | 15,4 | 1,9 | 73,1 | 7,7 | 2,3 | 12,3 | 8,1 | 69,6 | 7,7 |
| Use exclusions in contact with certain food types | 17,3 | 21,2 | 3,8 | 44,2 | 13,5 | 9,6 | 18,8 | 6,9 | 51,5 | 13,1 |
| Maximum quantity to apply on packaging around 1kg of food in order to remain compliant with all restrictions in worst case conditions and taking in account all IAS, NLS and NIAS which may be present or Maximum surface volume ratio. | 50,0 | 1,9 | 23,1 | 11,5 | 13,5 | 53,1 | 5,0 | 16,5 | 10,0 | 15,4 |
| Storage conditions and shelf life before food contact | 3,8 | 0,0 | 5,8 | 78,8 | 11,5 | 3,8 | 0,4 | 5,4 | 78,8 | 11,5 |
| The maximum time temperature during food contact | 34,6 | 17,3 | 26,9 | 13,5 | 7,7 | 45,4 | 14,6 | 17,3 | 13,5 | 9,2 |

Supplier Questionnaire - Latest version June 2023

**(4)** provide details on the use restrictions.

Suitability for direct physical food contact (DFC) / for use on the non direct contact side of food packaging (Non-DFC).

The maximum compliant area-volume ratio for a given dried / cured ink layer thickness - if applied as recommended - taking in account all IAS, NLS and NIAS substances which may be present.

The use exclusions in contact with certain food types. (e.g. fatty, moist, dry, pasty, acidic, with alcohol)

The use exclusions in relation to the food (in pack) treatment (conventional oven, microwave oven, radiation, sterelisation ...) at the food manufacturer or by the consumer.

Based on the chemical knowlegde of the supplier, an indication on the chemicals to avoid in the other FCMs carton makers are using ?

Recommendations related to the storage conditions and shelf life of the ink and of the finished carton before food contact.

The maximum time temperature during food contact.

**Discussion**

# Other useful information

## Supplier Questionnaire - Latest version June 2023

**More useful information and commitments.**

**(1)** Statement on presence and regulatory status of certain types of substances (Biocides, CMR, EDC, Epoxy derivates/BPA, GMO (origin of the used compounds ? EU ?), MOSH/MOAH, Nano, PAA's, PFAS (PTFE), Photoinitiators, Phtahaltes, SVHC, …)

Photoinitiators : Require compliance with EuPIA suitability of Photoinitiators and Photosynergists for food contact materials. (Version July 2020)

**(2)** Status with regard BSE/TSE risk

**(3)** Halal, Koscher, Vegan

**(4)** Prior to any change in the ink formulation, the ink manufacturer needs to inform well in advance the carton maker.

**Discussion**

## 2 Specific questions related to the EuPIA Guidance documents.

## 3. Testing conditions LT @ RT.

EuPIA Guidance on migration Test methods for the evaluation of substances in printing inks and varnishes for food contact materials. Version 03 05 2023

### 4.2.2. Selecting migration parameters

*A Migration conditions*

*Table 2: Worst Case migration (printed or non-printed side) testing conditions*

| **Food Type** | **Liquid - Moist** | | | | **Dry** | | | |
|---|---|---|---|---|---|---|---|---|
| Simulant | EtOH 95%* | | | | MPPO*** | | | |
| Food contact time [d] | < 1 | | > 1 | | < 1 | | > 1 | |
| Food contact temperature [°C] | < 40 | > 40 | < 40 | > 40 | < 40 | > 40 | < 40 | > 40 |
| Testing temperature [°C] ** | max 40 | max 60 | max 40 | max 60 | 40 | 60 | 40 | 60 |
| Testing time [d]** | 1 | 1 | 10 | 10 | 1 | 1 | 10 | 10 |

* Other simulants can be used for some specific applications (see also justified deviations, section 4.4).
** The temperature and time of the testing conditions may be adapted to the real contact conditions
*** MPPO is also recommended as simulant for high-temperature applications [7]. However, MPPO is known to overestimate migration of some migrants compared to real food, and a reduction factor or measurement in real food might be needed for compliance measurements [11] [12].

Regulation (EU) No. 10/2011 specifies three different testing regimes (10 d at 40°C, 10 d at 50°C, and 10 d at 60°C) dependent on product storage conditions. The regulation also states that substrates should not be altered by the applied conditions [13]. If this is case, please refer to section 4.4.

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**4.4. Justified deviations from the recommended methods**

- Thermal decomposition of ink/coating components during analysis has been reported, producing detectable artefacts: notable examples include some pigments/pigment additives, polyurethanes, photoinitiators and ATBC/tributyl aconitate.

EuPIA Follow up PIJITF 8/11

Mike Simoni (Chair EuPIA PIFOOD) 22/11

*"EuPIA commissioned a far ranging migration study which was done by Fraunhofer. From the test data we can see that a 10 day 40 C Tenax migration test is a good simulation for 6 months at room temperature.*

*Increasing the temperature to much more than 40 C is not a good option as this then significantly overestimates migration (references for this include the attached study done in Ghent).*

*To allow the accelerated migration test to simulate more than 6 months room temperature storage I would therefore recommend a 30 day 40 C Tenax migration test. I appreciate that this is not a standard test but this will based on the data that we have give the best simulation of ~1 year room temperature migration.*

*EuPIA does in time have a plan to update its migration testing guidelines (which is a public domain document available on the EuPIA website) to include learnings from our migration studies but as of now this is still in progress."*

Demonstrate equilibration is reached.
Analytical testing - Modelling : Rainer Brandsch / Olivier Vitrac ?

## 4. Mineral oil requirements in France.

French Decree MO

Ban limit at 0,1% for MOSH and MOAH in inks, problematic

Until the 31/12 2024 : MOAH where the mass concentration in the ink is > 1%
From the 01/01 2025 : MOAH if the mass concentration is > 0,1 % or if the concentration for compounds of 3-7 aromatic cycles is above 1 ppm.
MOSH if the mass concentration is > 0,1 %.

PIJITF (8/11) Possibility : compliance based on documents, use of white oils.
Note announced.

## 5. How to handle NIAS.

## 6. UTC limits in pigments.

EuPIA

20 key essential pigment Colour Indexes with PCB content potentially > 1ppm (as Unintentional Trace Contaminant UTC) at risk in view of POPs Regulation.

# 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<br>PB15:1-15:6 | PB76 | |
| Brown | | PBr23 | | | |
| Green | | | PG7 | PG36 | |
| Orange | PO34 | PO13 | PO43 | PO61 | PO36 |
| Red | PR2<br>PR112 | PR144<br>PR166<br>PR214<br>PR254 | | PR48:4<br>PR202<br>PR220<br>PR221 | PR5<br>PR170<br>PR184 |
| Violet | PV23 | | | | |
| Yellow | PY13<br>PY14<br>PY17<br>PY81<br>PY83 | PY12 | PY174 | PY93<br>PY95<br>PY109<br>PY110<br>PY128<br>PY138<br>PY168<br>PY183<br>PY191:1 | PY1<br>PY3 |

**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)

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

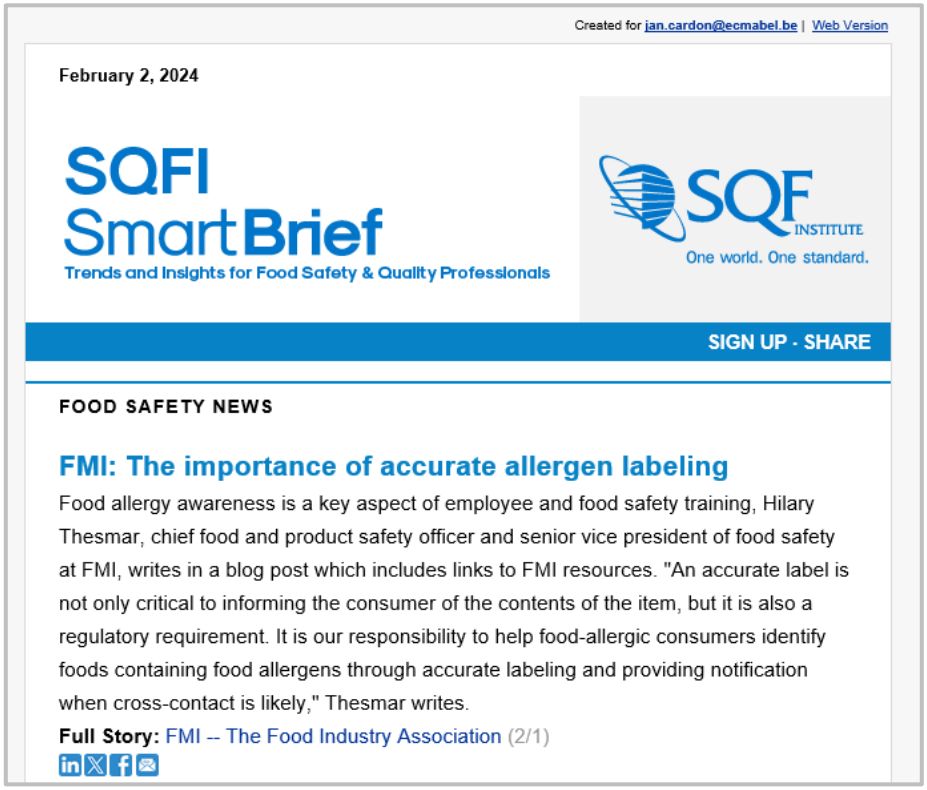

**Discussion** Use in carton sector ?
Availability pigments with lower UTC ?

# 7. Allergens in printing powders.


| FSSC 22000 Additional requirement 2.5.6: Management of Allergens |
| --- |
| **ECMA Guidance** |
| Requirements to the management of allergens for a (carton) packaging company are usually low. There will be no allergens present in the processes or products. One potential identified source might be starch based anti set-off spray powder used in offset printing. A declaration from the supplier is sufficient to exclude allergen content in those.<br><br>Further mitigation is implemented by excluding food and drink to be brought into the production areas by workers. A suitable canteen facility away from production should be available with provisions to store home brought food. Handwashing after breaks is implemented as part of the PRP program.<br><br>Declarations of allergens as relevant to the packed food may be included in print designs provided by the customers. It is important here for the carton manufacturer to document (non-) liability for any errors in print design.<br><br>In further converting process it is key to avoid risk of mix up in general and most importantly if a product line contains both allergen and non-allergen variants.<br><br>For comments in relation to responsibility for the graphic design : See BRCGS 5.2 Graphic design and artwork control (G) |

Statement from supplier shared by ECMA member

"For our products … the following applies : the mentioned products contain wheat starch, which is listed as a substance in Annex II of Regulation (EU) 1169/2011 of 25.11.2011. According to the information provided by our suppliers, we hereby confirm that the products contain less than 20 ppm gluten and are therefore considered gluten-free according to Codex Alimentarius Standard 118-1979."



Created for jan.cardon@ecmabel.be | Web Version

February 2, 2024

SQFI SmartBrief

Trends and Insights for Food Safety & Quality Professionals

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FOOD SAFETY NEWS

**FMI: The importance of accurate allergen labeling**

Food allergy awareness is a key aspect of employee and food safety training, Hilary Thesmar, chief food and product safety officer and senior vice president of food safety at FMI, writes in a blog post which includes links to FMI resources. "An accurate label is not only critical to informing the consumer of the contents of the item, but it is also a regulatory requirement. It is our responsibility to help food-allergic consumers identify foods containing food allergens through accurate labeling and providing notification when cross-contact is likely," Thesmar writes.

**Full Story:** FMI -- The Food Industry Association (2/1)

20 ppm in food ?
Required communication on presence in FCM ? WCC sufficient ?

Printing powders.
Allergen free alternatives ?

3. Approval minutes and short follow up from the Food Safety Committee 13/12/23.

**Follow up questions to FEICA** (Mail 17/01 Jana Cohrs & Alexandra Ross)

**Extra FFI internal background on the allergen case ?**

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

European Commission | **RASFF Window**

-- Help --

SEARCH | CONSUMERS | TRACES

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2024.0755 | Herbs and spices | food | MOAH (mineral oil aromatic hydrocarbons) in Vanilla powder from Madagascar | 2 FEB 2024 | | Netherlands | information notification for attention | serious |
| 2024.0666 | Other food product / mixed | food | MOSH/MOAH in chickpea flour from the United Kingdom, via the Netherlands | 30 JAN 2024 | | Germany | alert notification | potentially serious |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2024.0434 | Food contact materials | food contact material | Lead and phtalates in pizza box from Turkey | 19 JAN 2024 | | France | information notification for attention | serious |
| 2024.0303 | Food contact materials | food contact material | Phthalates in paper plates | 15 JAN 2024 | | France | alert notification | serious |
| 2024.0170 | Food contact materials | food contact material | Lead, phtalates and photoiniators in pizza boxes from Türkiye | 9 JAN 2024 | | France | information notification for attention | serious |
| 2024.0115 | Cereals and bakery products | food | Mineral oil components in rice from Pakistan, via Poland | 5 JAN 2024 | | Germany | alert notification | potentially serious |
| 2023.8886 | Herbs and spices | food | Mineral oil components in ground pepper from Belgium | 22 DEC 2023 | | Germany | information notification for follow-up | potential risk |
| 2023.8805 | Cereals and bakery products | food | Mineral oil components in rice from Pakistan, via Poland | 20 DEC 2023 | | Germany | alert notification | potentially serious |
| 2023.8636 | Food contact materials | food contact material | MOSH and MOAH in packaging of basmati rice from Pakistan | 14 DEC 2023 | | Germany | information notification for attention | potential risk |
| 2023.8465 | Herbs and spices | food | Mercury and mineral oil hydrocarbons in ground cinnamon from Vietnam via the Netherlands and Spain | 8 DEC 2023 | | Germany | alert notification | potentially serious |

# 5. Legal food safety developments.

## Review EU FCM legislation

Workshop E&Y - DG SANTE 15 March (Brussels & Online) 9h30-17h00

Objective workshop

Study supporting Impact Assessment.
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.

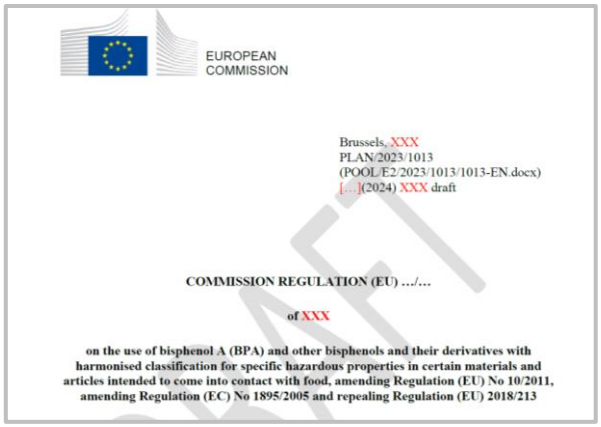
Present and discuss these options, our assessment of them, and potential implementation paths.

Agenda and details about the workshop by the end of this month.
Industry associations: extend this invitation to your business members and especially SMEs within your network.

Extra preparation of input may be needed.

## Commission published draft regulation on BPA.

Ban on intentional use.



EUROPEAN COMMISSION

Brussels, XXX
PLAN/2023/1013
(POOL/E2/2023/1013/1013-EN.docx)
[...](2024) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

on the use of bisphenol A (BPA) and other bisphenols and their derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011, amending Regulation (EC) No 1895/2005 and repealing Regulation (EU) 2018/213

Whereas

(9) In addition to the intentional use of BPA in the manufacture of certain food contact materials and articles, its unintentional presence in other food contact materials and articles and subsequent migration into food may also occur at levels of relevance to human health. Principally, it may be present as a contaminant in the input waste stream used to produce recycled materials including paper and board. This contamination can persist despite the application of cleaning and decontamination processes and may eventually be present in the final food contact article, including single use packaging. As business operators do not intentionally use BPA in such manufacturing processes and such contamination cannot be fully controlled; and in light of ongoing efforts in the Union to promote a circular economy, it is neither practical nor proportionate to prohibit the unintentional presence of BPA in recycled materials.

(10) Monitoring by manufacturers
Prohibition of BPA in thermal since 2020

*Article 1*

*Subject matter and scope*

1. This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2. This Regulation establishes specific requirements for food contact materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004 placed on the Union market, specifically as regards:

   (a) the use of 4,4'-isopropylidenediphenol ('BPA') (CAS No 80-05-7) in the manufacture of food contact plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers;

   (b) the use of other bisphenols and bisphenol derivatives listed in Annex VI, Part 3 of Regulation (EC) No 1272/2008 due to their harmonised classification as category 1A or 1B 'mutagenic', 'carcinogenic', 'toxic to reproduction' or category 1 'endocrine disrupting' for human health, in the manufacture of food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers;

   (c) the monitoring for any presence or migration of BPA from food contact BADGE-based heavy-duty varnishes and coatings, polysulfone resins for use in filtration membranes and paper and board containing recycled material.

Article 3 Prohibition of the use of BPA
Article 4 Specific requirements on the use of other bisphenols and bisphenol derivatives.

*Article 5*

*Monitoring and reporting of results*

1. A manufacturer placing on the Union market the following food contact materials and articles shall monitor for the presence of BPA and its migration from:

   (a) materials and articles on which BADGE-based heavy-duty varnishes and coatings is applied;

   (b) polysulfone resins for use in filtration membranes;

   (c) paper and board materials and articles containing recycled material.

2. The monitoring shall be carried out in accordance with rules on compliance, where applicable. For the purpose of point (c) the amount of BPA in the material may be determined using an extraction test.

3. Each business operator referred to in paragraph 1 shall carry out the monitoring on 5% of the batches of food contact materials and articles that it places on the market. The business operator shall select batches at random. When it is not possible to identify individual batches in case of continuous production, a sample shall be taken at a random time during a period of production that does not exceed 200 times the average residence time of the material in the production system.

4. If BPA is not detected in any batch or period of sampling within a 6 month period from the start of the monitoring or from the previous detection of BPA in accordance with this Article and provided that a minimum of 10 batches or periods of production was subjected to monitoring, the monitoring may be reduced to 1% of the batches or by 1000 times the average residence time, as applicable.

5. In case the results of the monitoring indicate the presence of BPA, the business operator referred to in paragraph 1 shall carry out an investigation to determine the source of the BPA with cooperation from other business operators in the supply chain and where necessary, follow-up actions to reduce or eliminate the presence of BPA in the food contact materials or articles that it places on the market, including changes to its production practices or changes to specifications of intermediate materials and articles obtained from suppliers.

6. A report of the monitoring referred to in paragraph 1 including the batch or period of sampling, the method of analysis used and result shall be submitted to the competent authority in the Member State where the food contact material or article was tested every 12 months from the date of entry into force of this Regulation. If BPA is found, its level shall be reported without delay to that competent authority and an outline of the planned remedial action shall be provided within 20 working days from the date on which a result is generated. The results of the remedial action shall also be reported once such action is implemented.

Article 7 Written declaration of compliance and supporting documentation

**Possibility to comment until the 8/03**

**Swiss Printing Inks Ordinance updated as of 1/02.** (amendment dated 8/12/23)

Part B list (unevaluated substances) of positive list in Annex 10 (packaging inks) will be deleted.

Other substances not listed on Part A can still be used if not carcinogenic, mutagenic or toxic to reproduction and migration is non-detect (0,01 mg/kg …).

DOC will be required, including adequate information on NIAS.

FSVO will come with a guidance document.

# 6. ECMA statement on testing conditions.


**Obtained additional information.**

JRC guidance

| | | |
|---|---|---|
| Food Serving Utensils for Cold/Ambient or Hot use | FSU/CAH1 | Cup, Glass, Drinkware |
| | FSU/CAH2 | Open flask, Carafe, Can, Jug |
| | FSU/CAH3 | Bottle |
| | FSU/CAH4 | Baby bottle, Teats |
| | FSU/CAH5 | Tableware, Plate, Dishware, Serving stand |
| | FSU/CAH6 | Food tray, Serving board, French fries box, Finger food bag, Snack box, Popcorn box |
| | FSU/CAH7 | Thermos flask, Isothermic drinking beaker |
| Food Serving Implements for Cold/Ambient use | FSI/CA1 | Ice cream scoop, Ice tongues, Ice cube tray |
| | FSI/CA2 | Specific use Cutlery and wine accessories: Cheese knife, Cheese slicer, Grapefruit knife, Salad cutlery, Tomato knife, Oyster knife, Butter curler, Honey dipper, Bar pestle, Wine tester, Bottle pourer, Wine chiller |
| | FSI/CA3 | Salt mill, Spice mill, Pepper mill, Herb mill, Salt shaker |
| Food Containers for Cold/Ambient or Hot use | FC/CAH1 | Lunchbox, Takeaway box, Pizza box |
| | FC/CAH2 | Container: Pasta container, Cheese cellar, Butter cellar, Can cover, Garlic/onion keeper, Egg to go box, Bread box, Biscuit box, Storage box, Bag/textile for storage, Foil (not for baking), Jar, Ice cream container |

European Commission

## Table 5A – Migration test conditions for paper & board kitchenware

| Main Class | Subclass | Use: cold (< 20 °C) | Use: Room Temperature | Use: hot (> 40 °C) | Use: storage (in months) | Sample prep: cut test specimen | Sample prep: intact article | Sample prep: part of it | Test type: actual use | Test type: article fill | Test type: migration cell | Test type: (total) immersion | check national legislation* | Food/Food simulant: food | A | B | C | D1 | D2 | E | SM Conditions (only food simulants): time | SM Conditions (only food simulants): Temp (°C) | S/V: Real | S/V: Real (infant/young) | S/V: 6 (V < 0.5L or V > 10L) | S/V: 6 impractical s/v | OM - check national legislation* | Notes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Food Serving Utensils | FSU/CA1 | x | x | | | y | x | | | x | y | | x | x | x | x | | | x | | 24 h | 40 | x | x | x | x | x | |
| | FSU/CA2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSU/CA3 | x | x | | @ | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 40 | x | | x | | x | |
| | | x | x | | ≤ 6 | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 50 | x | | x | | x | [2] |
| | | x | x | | > 6 | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 60 | x | | x | | x | [2] |
| | FSU/CAH1 | x | x | | | y | x | x | | x | y | | x | x | x | x | | | x | | 24 h | 40 | x | x | x | | x | |
| | | | x | x | | y | x | x | | x | y | | x | x | x | x | | | x | | 2 h | 70 | x | x | x | | x | followed by 24 h at 40 °C, if used for storage |
| | FSU/CAH2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSU/CAH3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSU/CAH4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSU/CAH5 | x | x | x | | y | x | | | x | y | | x | x | x | x | | | x | | 2 h | 70 | x | x | x | x | x | |
| | FSU/CAH6 | x | x | x | | y | x | x | | x | y | | x | x | x | x | | | x | | 2 h | 70 | x | x | x | x | x | |
| | FSU/CAH7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Food Serving Implements | FSI/CA1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSI/CA2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | FSI/CA3 | x | x | | ≤ 6 | | x | x | | x | | x | x | x | | | | | | x | 10 d | 50 | | x | | x | x | [2] |
| | | x | x | | > 6 | | x | x | | x | | x | x | x | | | | | | x | 10 d | 60 | | x | | x | x | [2] |
| | FSI/CAH1 | x | x | x | | x | x | x | | | | x | x | x | x | x | | | x | | 2 h | 70 | | | | x | x | |
| | FSI/CAH2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Food Containers | FC/CAH1 | x | x | x | | y | x | x | | x | y | | x | x | x | x | | | x | | 2 h | 70 | x | | x | | x | followed by 24 h at 40 °C, if use for storage [OM2] |
| | | x | x | x | @ | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 40 | x | | x | | x | |
| | FC/CAH2 | x | | | | y | x | x | | x | y | | x | | | | x | | | | 10 d | 5 | x | | x | | x | |
| | | x | x | | @ | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 40 | x | | x | | x | |
| | | x | x | x | ≤ 6 | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 50 | x | | x | | x | [2] |
| | | x | x | x | > 6 | y | x | x | | x | y | | x | x | x | x | | | x | | 10 d | 60 | x | | x | | x | [2] |

* **When no national legislation is available, national recommendations, or Council of Europe recommendations, or other relevant guidelines shall be taken into account for compliance assessment.**

[1] cf. Table 2 of Annex V

[2] use (10d, 40°C ) if equilibrium is reached [cf. Reg. 10/2011 Annex V, Chapter 2 § 2.1.4.e & Amendment 2016/1416 ]

@: see Table: Rational

"y": "migration cell" applies to "cut test specimen" only

SM, OM: Specific migration, Overall Migration

s/v: surface-to-volume ratio to calculate final migration result

Food Simulants: A (Ethanol 10 % v/v); B (Acidic acid 3 % w/v); C (Ethanol 20 % v/v); D1 (Ethanol 50 % v/v); D2 (Vegetable oil); E (poly(2,6-diphenyl-p-phenylene oxide)) [cf. Reg. 10/2011 Annex III]

*version June 2023*

EURL European Union Reference Laboratory for Food Contact Materials

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## Rational for the selection of test time and temperature (Specific Migration)

| time | temperature | Sub-class | Rational/justification |
|---|---|---|---|
| 10 d | 40 °C | FPU/CAH5<br>FPU/CAH8<br>FSU/CAH3-4<br>FSU/CA3<br>FSI/CAH2<br>FC/CAH1-2 | According to Regulation 10/2011,<br>- for utensils in contact with food for more than 30 days at refrigerated or frozen temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes;<br>- for utensils in contact with food for up to 30 days at room temperature. |
| 10 d | 50 °C | FSU/CA3<br>FSU/CAH3<br>FSI/CA3<br>FSI/CAH2<br>FC/CAH2 | According to Regulation 10/2011, for utensils in contact with food for more than 30 days but less than 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T- 70)/10) minutes, these test conditions apply. |
| 10 d | 60 °C | FSU/CA3<br>FSU/CAH3<br>FSI/CA3<br>FSI/CAH2<br>FC/CAH2 | According to Regulation 10/2011, for utensils in contact with food for more than 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T- 70)/10) minutes, these test conditions apply. |

**Appropriate test conditions for the substrate ?**

PTS studies : no reply so far.
CEPI : Reference to JRC and Plastics Regulation. No indication up to which temperature P&B can be tested.

Eva Lindström (Author of testing chapter CEPI/CITPA Guideline) :

- 10d 40°C commonly used.
- Testing at 40°C is accelerating the migration compared to 25 °C
- Tests for the board were done proving equilibrium is reached after 10 days.
- 10d 60 °C is not feasible for treated papers … polymers do not withstand the higher temperatures.
- For paper and board untreated paper ethanol as an extraction solvent not appropriate. Isooctane most suitable to mimic fatty food …
- "You might need to do some tests to show that equilibrium is reached with 40 °C 10 days, the chance to succeed is quite good as migration mechanisms for paper and abord is very different from that for plastics, much faster."

**Draft statement.**

EUROPEAN CARTON MAKERS ASSOCIATION

## ECMA STATEMENT ON TESTING CONDITIONS

**February 2024**

This statement reviews ways to test the migration of cartons stored for a long term at room temperature. In recent months, this topic has been discussed at length within the ECMA Food Safety Committee and with the various 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).

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.

In view of the misconception that cartons should be tested according to the approaches in the Plastics Regulation (EU) No 10/2011, 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, customers tend to require for long-term storage, testing at room temperature for 10 days at 60°C.

This is, however, 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 with leading food safety experts from the European associations representing the suppliers of the FCM materials, carton makers are using.

In the 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 and a contact time above 1 day, this table is indicating MPPO testing at 40 °C for 10 days.

In fact, this derogation of testing at a lower temperature is also 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 considers appropriate to perform compliance tests for regular cartons stored for a long term at room temperature, at 40 °C.
For accelerated tests a pragmatic compromise approach may be, to test for 30 days until scientific evidence can demonstrate that the migration of the present substances has reached equilibration in 10 days.

**Expert involvement.**

7. Update sustainability related topics.
8. Miscellaneous.

ECMA Presentation at PTS Paper and Board for food contact conference. (6-7/03)
"Current food safety topics and developed guidelines within the carton sector."

*Thank you for your attendance and contributions !*