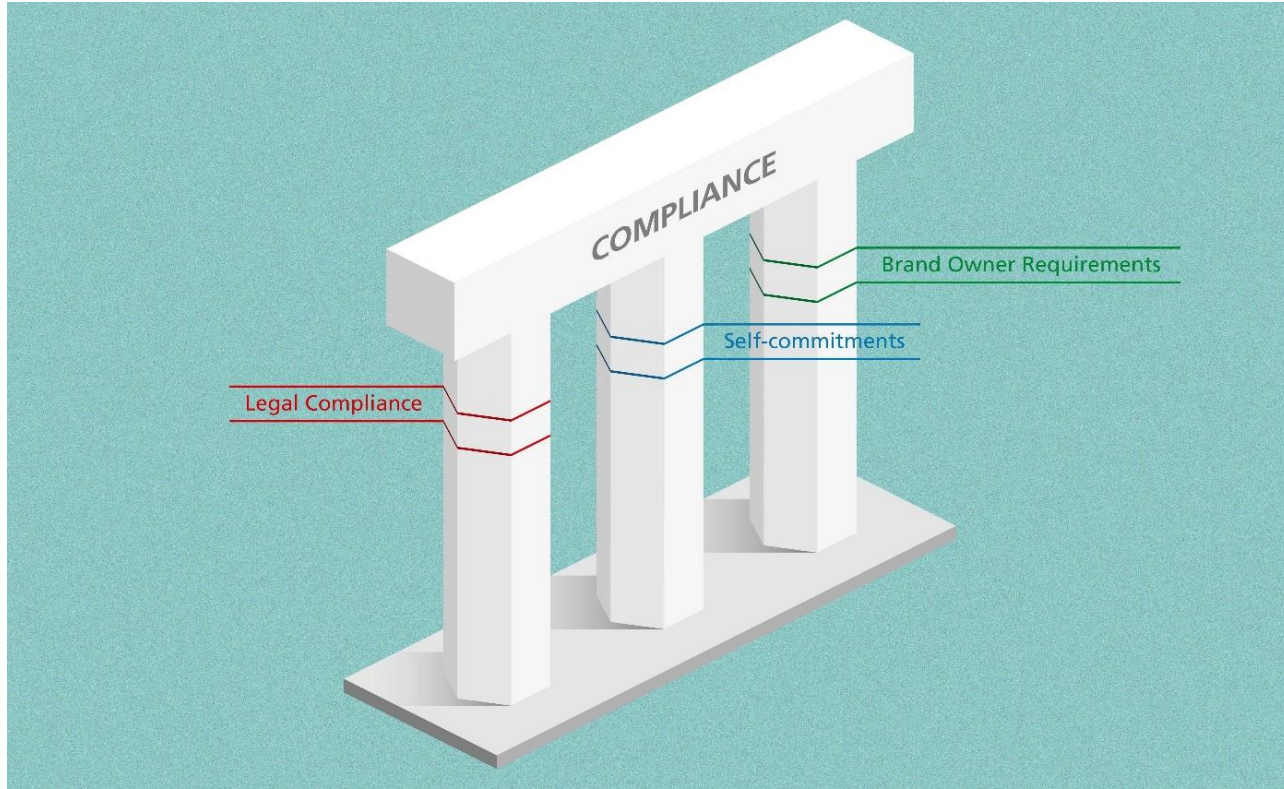


## Compliant printed food contact materials – EuPIA's contribution

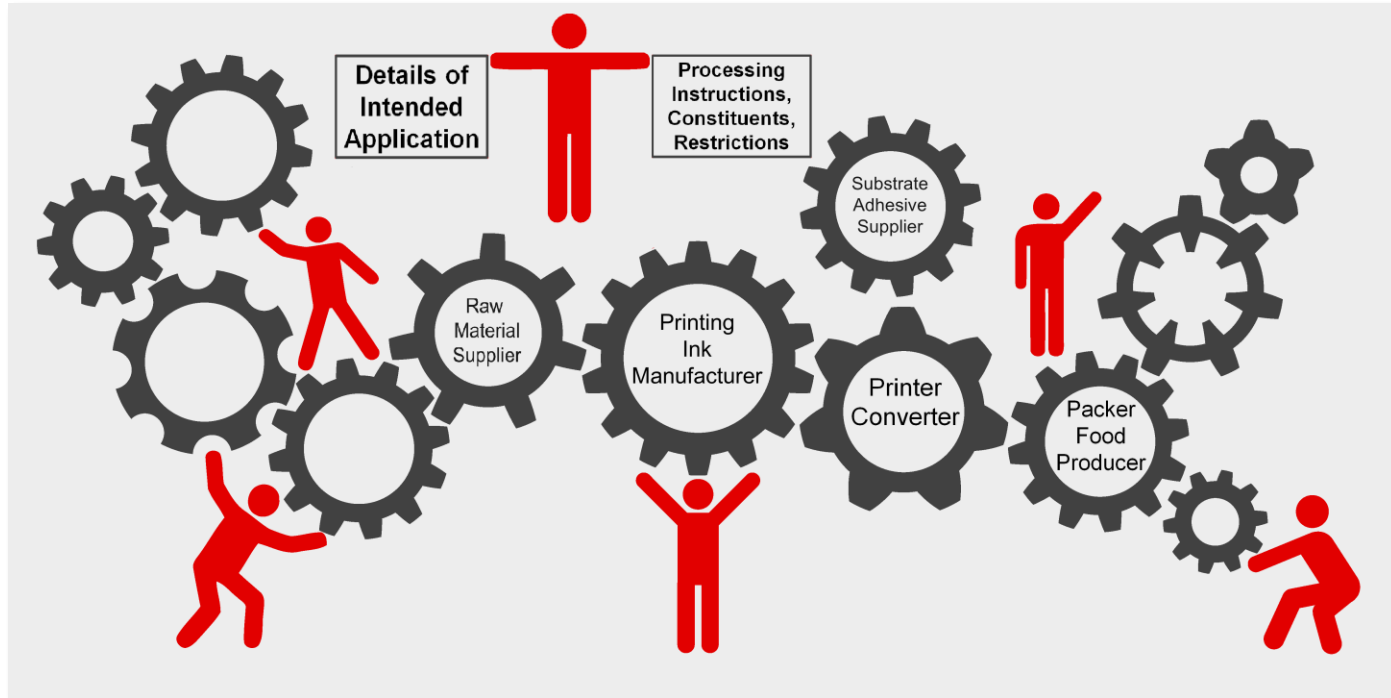


# FCM inks: The three Pillars of Compliance



# Exchange of Information along the Supply Chain

Co-operation and information sharing among all partners in the food packaging supply chain





## Criteria (hazard categories) for exclusion of a raw material



### GROUP A

Acute Toxicity Cat. 1 & 2 [H300, H310, H330]

Acute Toxicity Cat. 3 (inhalation)  
[H331]

Carcinogen or Mutagen Cat. 1A & 1B  
[H350, H340]

Toxic to Reproduction Cat. 1A & 1B [H360]  
(*non-threshold substances*)

STOT Single Exposure Cat. 1 [H370]

### GROUP B

Acute Toxicity Cat. 3 (oral, dermal)  
[H301, H311]

Toxic to Reproduction Cat. 1A & 1B [H360]  
(*if threshold exists*)

STOT Repeated Exposure Cat. 1 [H372]

## Substitution principle by default

If substitution not possible in the short term, exemption is possible according to the clearly defined and managed procedure for a limited period of time

- **Legal background**

Regulation (EC) No. 1935/2004 (specific European harmonised legislation on Printing Inks and Coatings still awaited)



- **Scope**

Printing Inks and Coatings applied to the Non-Food Contact Surface of Food Contact Materials (FCM)

- **Content**

- Responsibilities and Requirements
- Selection Scheme for Raw Materials
- Test Methods and Models for printed and/or coated FCM

- **Legal background**  
Regulation (EC) No 2023/2006
- **Scope**  
Printing Inks and Coatings for Food Contact Materials (FCM)
- **Definition**
  - GMP is meant as a useful and specific extension of management system standards such as EN ISO 9001
  - GMP is not meant as an independent management system standard
- **Content**
  - Requirements and Measures for FCM Inks and Coatings to meet customer and applicable regulatory obligations



Specific Measures and Procedures are described for...

- General requirements (Quality Management, Equipment,...)
- Risk Assessment and Management (FMEA, Migration and Worst-Case Calculation...)
- Hygiene Management
- Identification, Traceability and Recall
- Change Management
- Resource Management (Raw Material Selection Scheme,...)
- Product Realisation (Product selector,...)
- Measurement, Analysis and Improvement





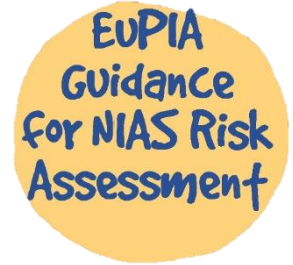
Specific guidance for printing inks for FCMs (non-DFC and DFC)

Recommended methods:

- „Worst case“ calculation and migration modelling
- Migration testing (Preparation of test samples, selecting migration parameters, Analytical identification and quantification)



- An IAS can become a NIAS down the packaging chain
- NIAS risk assessments are foreseen for substances which have not been officially evaluated yet
- 10 ppb limit is a detection limit not based on any hazard assessment
- Higher safety due to:
  - Identification of substances with genotoxic potential
  - Self-derived SMLs instead of detection limits
- Declaration of NIAS in the SoC



# EuPIA Suitability List of Photoinitiators and Synergists for energy curing FCM inks and coatings

- The Suitability List is widely referenced by the supply chain and by brand owners as a requirement for inks and coatings for their food packaging
- The List is constantly reviewed and has been updated to reflect the current Swiss Ink Ordinance and remove materials recently subject to the EuPIA Exclusion Policy
- Procedure defining how new materials can qualify for listing and the status of existing materials adjusted recently launched

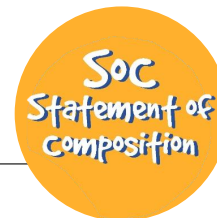


# The „Statement of Composition“

- Contains a table of potential migrants which are “used or known to be present”, including NIAS and NLS
- In line with the „Recommendation for adequate information on non-plastic intermediate materials (inks, adhesives, coatings)“, given in the Union Guidance on regulation 10/2011
- EuPIA Customer Guidance Note available



## Table of potential migrants (example)



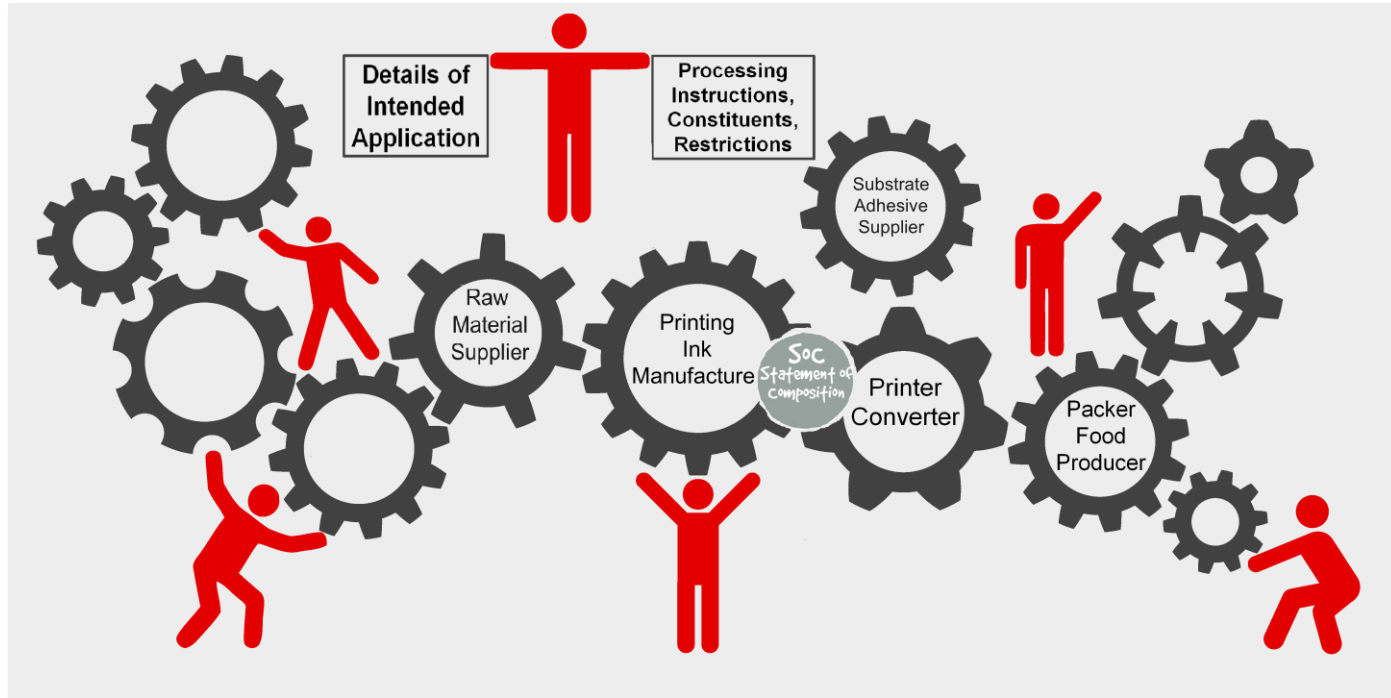
| CAS No            | PM Ref No    | FCM No     | Name                             | Restrictions and specific migration limits (SML) in [mg/kg] |                            | Regulation (EC) No 1333/2008, No 1334/2008 | Maximum amount in the dried ink film in [%] | Comments           |
|-------------------|--------------|------------|----------------------------------|---|----------------------------|--|---|--------------------|
|                   |              |            |                                  | Regulation (EU) No 10/2011                                  | Swiss Ordinance 817.023.21 |  |   |                    |
| 128-37-0          | 46640        | 315        | 2,6-di-tert-butyl-p-cresol (BHT) | 3   | 3                          | E 321                                      | 0.25%                                       |                    |
| 8001-22-7         | 24520        | 524        | soybean oil                      | (60)  | (60)                       |  | 20  |                    |
| <u>xxxx-xx-x</u>  | <u>xxxxx</u> | <u>xxx</u> | <substance X>                    | (60)  | (60)                       |  | 15  |                    |
| <u>yyyy-yy-y</u>  | <u>yyyyy</u> | <u>yyy</u> | <substance Y>                    | SML(T) = 6  | SML(T) = 6                 |  | (VR)  | reactive substance |
| <u>zzzzz-zz-z</u> | <u>zzzzz</u> | <u>zzz</u> | <substance Z>                    | 0.05  | 0.05                       |  | (VR)  | residual monomer   |
|                   |              |            |                                  |   |                            |  |   |                    |

(60) = 60 mg/kg food = Default Migration Limit for evaluated substances when no specific restriction is published.

VR = The amount of volatile or reactive substances in the print is under the control of the converter.

# Exchange of Information along the Supply Chain

The “Statement of Composition” is a key document in the food contact materials supply chain communication



# Thank you for your attention!

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