Printing Food Packaging

Packaging Safety - Constraints and solutions

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Food compliance is one of the most challenging parameters to get the right packaging for food

- Flexo in Asia was mainly dedicated to print personal care packaging
- Printing food packaging is increasing in Asia
- A food compliance crisis can ruin a brand reputation so it’s very important to take care of this aspect
- Following several major crisis, the Chinese regulation is becoming more and more stringent and the food compliance aspect cannot be ignored in China
It’s more than having raw materials complying with regulations

Raw materials must comply with regulation but

➢ Potential break down under light or thermal treatment is as important

➢ and migration must be carefully monitored
What is Migration – Overview

**MIGRATION** is a substance transfer from the packaging into the packed good
… it can happen via:

- Set-off (rolls, stacks, piles)
- Diffusion across the materials
- Gas Phase Transfer

… depends on:
- ink / varnish formulation
- substrate and design of the packaging
- printing conditions (drying, speed, …)
- the final use (type of good, sterilisation, …)
- the storage conditions (temperature, time, pressure)
  …
What are the permissible migration thresholds?

… they depend on documentation of toxicological data, and of subsequent toxicological expertise by the European Food Safety Authority EFSA

- **Non evaluated substances**
  - tox data not existing

- **Evaluated substances**
  - 3 favorable mutagenicity tests
  - 90 days Feeding Study --> X ppb

X = depends on tox expert judgement
Permissible migration is very low

SML’s for evaluated substances: some ppm - down to 10 ppb

Threshold for non-evaluated substances: 10 ppb

Sugar cube (2.5 g) dissolved in:

- 0.25 l Cup
- 2.5 l Bottle
- 2500 l Truck
- 2,5 Million l Tank ship
- 2,5 Billion l Dam
- 2,5 Trillion l lake

10 Gram per Kilogram (1%)
1 Gram per Kilogram (1%)
1 Milligram per Kilogram (1ppm)
1 Microgram per Kilogram (1ppb)
1 Nanogram per Kilogram (1ppt)
1 Picogram per Kilogram (1ppq)

Examples for values:
- Alcohol in drinks
- Alcohol in blood
- Nitrate in water
- Heavy metal in water
- Dioxine in ground
- Dioxine in breast milk
What can happen – Worst Case Calculation : = 100% substance transfer

<table>
<thead>
<tr>
<th>Content of migrant in dried ink layers, applied at 100% area coverage</th>
<th>Typical example of migrant</th>
<th>Max. migration with 6 dm²/kg food (&quot;EU cube 10x10x10 cm, 1 kg food&quot;)</th>
<th>Max. Migration with small package (case 40 g food in pouch 10x3x1.5 cm = 1 dm², 25 dm²/kg)</th>
<th>Evaluated substances</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With 3 g/m² dry ink</td>
<td>With 5 g/m² dry ink</td>
<td>With 3 g/m² dry ink</td>
<td>With 5 g/m² dry ink</td>
</tr>
<tr>
<td>25%</td>
<td>ATBC (Plasticizer, solvent based inks)</td>
<td>45 mg/kg</td>
<td>75 mg/kg</td>
<td>187 mg/kg</td>
</tr>
<tr>
<td>10%</td>
<td>DEHA (Plasticizer, solvent based inks)</td>
<td>18 mg/kg</td>
<td>30 mg/kg</td>
<td>75 mg/kg</td>
</tr>
<tr>
<td>2%</td>
<td>Erucamide (Slip Agent, solvent based inks)</td>
<td>3.6 mg/kg</td>
<td>6 mg/kg</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>2%</td>
<td>Dimethylaminoethanol (neutralizing agent, water based inks)</td>
<td>3.6 mg/kg</td>
<td>6 mg/kg</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>0.02%</td>
<td>Benzoisothiazolinone (biocide, water based inks)</td>
<td>0.036 mg/kg</td>
<td>0.06 mg/kg</td>
<td>0.15 mg/kg</td>
</tr>
<tr>
<td>5%</td>
<td>Benzophenone (photoinitiator in UV inks not intended for food packaging)</td>
<td>9 mg/kg</td>
<td>15 mg/kg</td>
<td>37 mg/kg</td>
</tr>
</tbody>
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What can happen – Worst Case Calculation : = 100 % Substance transfer

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<td>With 5 g/m² dry ink</td>
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</table>

### Non-evaluated substances

<table>
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<tr>
<th>25 %</th>
<th>Mineral oil (oleoresinous offset inks not intended for food packaging)</th>
<th>45 mg/kg</th>
<th>75 mg/kg</th>
<th>187 mg/kg</th>
<th>312 mg/kg</th>
<th>0.001 mg/kg (10 ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>Low molecular photoinitiators (UV curing ink not intended for food packaging)</td>
<td>9 mg/kg</td>
<td>15 mg/kg</td>
<td>37 mg/kg</td>
<td>62 mg/kg</td>
<td>10 ppb</td>
</tr>
<tr>
<td>0.5%</td>
<td>Acetyacetone (from adhesion promoter of solvent based ink not intended for food packaging)</td>
<td>0.9 mg/kg</td>
<td>1.5 mg/kg</td>
<td>3.7 mg/kg</td>
<td>6.2 mg/kg</td>
<td>Not detectable</td>
</tr>
</tbody>
</table>
Conclusion

• Exceeding of the applicable threshold cannot be excluded

• Real Migration depends

  not only on the ink type and formulation
  but on

  the combination of all components
  and the design of the final packaging
2009: What happened, when Benzophenone and 4-Methylbenzophenone migrated....

.. only an inner pouch with alu film would serve as barrier
2009:
What happened, when Benzophenone from Sleeves migrated...

... The bottle was not a barrier
Processes involving the application of printing inks to the non-food contact side of a material or article

1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
   (a) through the substrate or;
   (b) by set-off in the stack or the reel,

in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:
   (a) through the substrate or;
   (b) by set-off in the stack or reel,

in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

Conclusion:

✓ The final confirmation of legal compliance cannot be delegated to the ink maker
The 6 steps and responsibilities for a perfect food packaging

1. PACKAGING SPECIFICATIONS BY THE FOOD INDUSTRY
   - Packaging Specifications

2. PACKAGING CONCEPTION BY THE CONVERTER
   - Process Conception

3. INK FORMULATION BY THE INK MANUFACTURER
   - Ink Formulation

4. ADVICE ON USE BY THE INK MANUFACTURER
   - Advice on Use

5. VALIDATION OF THE COMBINATION INK/MATERIALS/PROCESS BY THE PRINTER
   - Process Validation

6. FINAL VALIDATION BY THE FOOD INDUSTRY
   - Final Validation

What is Migration
Regulations
Who is Responsible for What

1. PACKAGING SPECIFICATIONS BY THE FOOD INDUSTRY
2. PACKAGING CONCEPTION BY THE CONVERTER
3. INK FORMULATION BY THE INK MANUFACTURER
4. ADVICE ON USE BY THE INK MANUFACTURER
5. VALIDATION OF THE COMBINATION INK/MATERIALS/PROCESS BY THE PRINTER
6. FINAL VALIDATION BY THE FOOD INDUSTRY
Specifications by the food industry

Parameters which influence the Migration and the Health Risk - Necessary information:

- Purpose of the packaging (infant / adult food)
- Type of food to be packed (dry, liquid, pasty)
- Description and function of all components of the packaging system (i.e. self-adhesive label, existence of a barrier film, …)
- Packaging type and structure (inner wraps, overwraps, nature of the material layers, …)
- Size of the Packaging (Surface-Volume Ratio)
- Nature of the print on the article
- Time and pressure in stack or reel
- Further treatment (pasteurisation, baking oven, microwaving,…)
- Expected maximum shelf life
- ……
The 6 steps and responsibilities for a perfect food packaging:

1. PACKAGING SPECIFICATIONS BY FOOD INDUSTRY

2. PACKAGING CONCEPTION BY THE CONVERTER

3. INK FORMULATION & MANUFACTURING BY THE INK MANUFACTURER

4. ADVICE IN USE FROM THE INK MANUFACTURER

5. VALIDATION OF THE COMBINATION INK/MATERIALS/PROCESS BY THE PRINTER

6. FINAL VALIDATION BY THE FOOD INDUSTRY
Packaging Conception by the Converter

Are done under the responsibility of the printer:

- The selection of the substrate and the other materials,
- The graphic design (the type and amount of ink)
- The control of the printing and converting process parameters.

A risk assessment to quantify the migration potential must be done, considering the packaging type.

These information as well as the packaging specifications must be transferred to the ink maker.
Risk Assessment by Packaging Category

- The converter identifies the packaging category
- the ink maker can advise per category on
  - ink-related migration risks
  - about migration risk per ink type (solvent-based, water-based, oleoresinous offset, UV-curing)

See SIEGWERK Customer Guidance: Printing Inks for Food Packaging

Application matrix with:
- Packaging Category
- Migration Risk Yes / No
- About inks for this Application
- Validation Measures recommended to the Printer
The 6 steps and responsibilities for a perfect food packaging:

1. **Packaging Specifications** by the food industry

2. **Packaging Conception** by the converter

3. **Ink Formulation** by the ink manufacturer

4. **Advice on Use** by the ink manufacturer

5. **Validation of the combination Ink/Materials/Process** by the printer

6. **Final Validation** by the food industry

**What is Migration and Regulations**

**Who is Responsible for What**

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**Advice on Use**

**Process Validation**

**Validation Finale**
EuPIA Guideline – The EU-wide Industry Standard for Raw Material Selection

Raw Materials

- Authorised for direct food contact use
  - Yes: Can be used
  - No

Compliance with Exclusion Criteria

- No

Raw Material is a dye

- Yes

Compliance with purity requirements

- Yes

Molecular Weight > 1000 Dalton

- Yes: Can be used
- No

Migration <10 ppb

- Yes: Can be used
- No

Migration <50 ppb

- Yes

Risk assessment

- Adequate Tox data
  - Yes
  - No: Rejection

- No

Substances with MW < 1000 Dt present in packaging inks which have insufficient toxicological data shall be subject to the following target migration limit deadlines:

- 50 ppb migration December 2010
- 10 ppb migration December 2015

Evaluation of Migration

a) Experimental testing
b) Alternative scientific tools

- No

Yes

- Listed in existing EU or national legislation on food contact materials
- Evaluated by EFSA/SCF or other bodies e.g. JECFA, WHO, FSANZ
- National Recommendations (e.g. BfR)
direct food contact materials
- Council of Europe Resolutions for
- FDA regulations
- Food additives regulations

Yes
A secure approach in the Raw Material Selection

A strict and global SIEGWERK Raw Material Introduction Process
Overall principles of SIEGWERK’s Raw Material Selection and Ink formulation

- Exclusion of toxic and CMR* substances
- Pigment Selection according to strict Purity Criteria

Formulation
- Ensuring Worst Case Calculation per migrant, based on:
  - Standard packaging size (surface-volume ratio 6 dm²/kg)
  - Upper standard dry ink film weight 3 g/m²

and/or
- Exemplary migration testing

Printer can be assured SIEGWERK’s homework is done

Specific final packaging made under control of the printer and food packer can meet the applicable migration thresholds per substance

*CMR: Carcinogenic, Mutagenic, toxic for Reproduction
The 6 steps and responsibilities for a perfect food packaging

1. PACKAGING SPECIFICATIONS BY THE FOOD INDUSTRY

2. PACKAGING CONCEPTION BY THE CONVERTER

3. INK FORMULATION BY THE INK MANUFACTURER

4. ADVICE ON USE BY THE INK MANUFACTURER

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What is Migration
Regulations
Who is Responsible for What

Packaging Specifications
Process Validation
Ink Formulation
Advice on Use

1
2
3
4
5
6

SIEGWERK
1. Pertinent and didactic Technical Data Sheets

2. Formal “Statements of composition”:
   - Information on the evaluated substances and their SML’s
   - Enables the converter to issue his declaration of conformity for the printed packaging

3. “Ingredient disclosure” process to allow risk assessment for non-evaluated substances:
   - To professionals of converters, to migration testing labs, in specific cases to end-users
   - Done on basis of previous confidentiality agreement
   - Includes all ingredient substances with migration potential
The 6 steps and responsibilities for a perfect food packaging

1. Packaging Specifications by the Food Industry
2. Packaging Conception by the Converter
3. Ink Formulation by the Ink Manufacturer
4. Advice on Use by the Ink Manufacturer
5. Validation of the Combination Ink/Materials/Process by the Printer
6. Final Validation by the Food Industry
Verification of the conformity of the packaging: How SIEGWERK can assist you

Advice and information on the necessary measures and/or tests:

- **Migration**

  ✓ **SIEGWERK Customer Guidance: Printing Inks for Food Packaging**
    
    Application matrix with:
    - Packaging Category
    - Migration Risk Yes/No
    - About inks for this Application
    - Validation Measures recommended to the Printer

  ✓ **Worst Case calculation (i.e. solvent based inks)**

  ✓ **Exclusion of standard oleoresinous sheetfed and standard UV inks**

  ✓ **Practical migration test (for the oleoresinous and UV Low Migration inks)**
    
    - Sampling procedure
    - Recommendations of suitable migration testing labs knowing Siegwerk inks, in particular Institut Kuhlmann
    - Interpretation of the final result

- **Sensory Tests**

  ✓ **Panel of SIEGWERK testers qualified for exemplary testing:**
    
    - Robinson Test
    - Sniff test
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What is Migration
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Who is Responsible
for What
Final validation by the packer/filler of the packaging

The food industry (the fillers) are responsible for

✓ the final approval of printer’s specifications on the use, such as:
  - type or types of food with which it is intended to be put in contact;
  - time and temperature of treatment and storage in contact with the food;
  - ratio of food contact surface area to volume used to establish the compliance of the material or article;

✓ own controls for migration to ensure compliance where delegated on the basis of the compliance documents delivered by the printer

  ▪ In particular the Declaration of Conformity
Thank you for your attention!