The Safety Assessment of Substances used in Printing Inks for Food Contact Materials

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EuPIA in a Nutshell

- **European Printing Ink Association**
- Founded in 2003
- Operates under the umbrella of CEPE, the European Council of the Paint, Printing Ink and Artists’ Colours Industry
- Represents > 80 manufacturers of printing inks and varnishes in > 160 manufacturing sites
- Represents > 90% of ink sales in Europe (2016: 962,000 tons; 3.05 billion €)
- Employs ~ 12,000 people
- Membership: Every member of a National Association representing the printing ink industry is automatically a member of EuPIA (dual membership principle)
What are Printing Inks?

a. Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with

b. Other coloured or uncoloured overprint varnishes/ coatings or primers which are normally applied in combination with a) in order to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip/friction properties

Printing inks do not include coatings which are applied with the prime objective of enabling the material or article to achieve a technical function such as heat sealing, barrier, corrosion resistance, as opposed to a graphic effect, even though they may be coloured.
Some Printing Ink Specific Facts

- High number of substances are needed in printing inks
  - Many of those substances are not used in Plastic Materials and therefore not fully evaluated and part of the Union list

- Printing inks are usually applied on the non-food contact side of an FCM, however migration of ink film ingredients may happen though the food contact layer.

- Substance transfer may also occur via set-off from the printed outer side to the food contact surface in the stack or the reel
Some Printing Ink Specific Facts

• Analytical methods are not available to demonstrate no migration at LOD of 10 ppb for many substances

• Migration methods for non-plastic materials are not harmonised. Also some migration methods for plastic materials are unsuitable and give misleading results (Tenax @ 60 °C)

• The ink industry and the printing industry are very diverse:
  – Few very large companies and many medium or very small enterprises
  – Also small and medium size companies must be able to fulfill the legal and/or industry regulations
• In the absence of European harmonized rules for inks for food contact materials EuPIA has developed their own guidance.

• EuPIA is not in favour of national regulatory initiatives

• EuPIA welcomes DG SANTE’s intention to issue a specific measure on printed food contact materials, and offers support in its development.
Key EuPIA Concepts

EuPIA Exclusion Policy

EuPIA GMP

EuPIA Guidance for RA of NIAS/NLS

EuPIA members Self Commitments

EuPIA Suitability List of Photo-Initiators

Statement of Composition
EuPIA Exclusion Policy

• Applies to all types of printing inks for all types of printing processes for all types of applications

• For 20 years EuPIA’s Exclusion List for Printing Inks and Related Products has been an established tool to enhance both safety and the image of the printing ink industry

• In September 2015 it was replaced by the EuPIA Exclusion Policy for Printing Inks and Related Products

• By default, highly hazardous raw materials, including those known to be carcinogenic, mutagenic or toxic for reproduction, are not permitted for use.
The Exclusion Policy uses the CLP classification rules as criteria

**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 [H350] (if threshold exists)
- STOT Repeated Exposure Cat. 1 [H372]

**Exemption from substitution** can be granted where a material cannot be replaced in the short term for a specific application:

- **Group A** with the explicit approval of EuPIA Technical Committee  
  *(exemptions listed in Annex 2 of Policy)*
- **Group B** self-assessment of safe use by member company
- In both cases members must report to EuPIA secretariat, who monitor application of procedure
Step 1: Raw Material Selection

• Key to know the ingredients in the ink raw materials.

**Raw Material Compliance Questionnaire**

• Standard proposal for EuPIA members for information request from raw material suppliers

• Member companies can use the proposed documents or add more questions

• The information received from suppliers, sometimes together with own analytical analyses is the basis for our safety assessment and provision of further information in the supply chain.
- **Used (intentionally added) substances** must
  1. Comply with the Exclusion Policy
  2. Should be officially listed
     - as food additive, or
     - as substance in the Union List, or
     - as ink ingredient according to the Swiss Ordinance, or
     - in other national substance lists (BfR, Warenwet …)

- **NIAS and non-listed substances**
  - Risk assessment should be done using the EuPIA guidance, which follows the principles of Art 19 of the Plastic Regulation
• EuPIA developed the „EuPIA Guidance for Risk Assessment of NIAS and NLS in Printing Inks for Food Contact Materials”, 2017

• **Hazard Identification** in 3 steps:

  1. Fully evaluated substances
     - SML values from Union list, Swiss Ordinance or evaluations of MS authorities

  2. Self derived TDI or SML values based on literature Tox data (for example REACH)
     - Derived from NOAEL, DNEL<sub>long-term oral general population</sub>, TDI Data
     - Studies must be of sufficient quality (Klimisch Score I or II)
     - Assessment Factor of 10 x 10 as minimum

  3. Self derived TDI or SML values based on TTC concept
     - Exclude genotoxic substances
     - Cramer Class I, II or III with respective Exposure Limits
     - ToxTree as proposed model
Step 4: Risk Assessment - Exposure

- **Exposure Identification**
  1. EU std. cube model if appropriate
     - Worst case calculation
     - Modelling
     - Testing
  2. EFSA Food Consumption database (more realistic consumption data)
  3. FACET (consumption plus packaging information)
NIAS/NLS Risk Assessment, pt. I

Substance Identification

- Has substance SML, TDI or other official approvals/restrictions?
  - Yes
  - No: Collect & examine available tox data

- Are tox data sufficient to establish absence of genotoxicity?
  - Yes
  - No: Any structural alert for genotoxicity?
    - Yes
    - No: Substance suitable for TTC approach? (excludes substance groups)

- Known/potential contaminant
  - Manufacturing process
  - Chemical assessment
  - Supplier information
  - Analytical data
  - Migration data

- Is exposure below restriction (le TDI) & migration below SML?
  - Yes
  - No: Refine exposure estimates

- Reformulate
  - Remove raw material
  - Cleaning in production
  - Reduce migration
  - Limit exposure
  - Downstream user communication

Absence of gene mutation & structural & numerical chromosome abnormalities
- Ames test
- Micronucleus test
- Klimisch 1 or 2

Substance identity & structure is known
- Not expected to bioaccumulate
- Substance adequately represented in database:
  - Not an inorganic, metal or organometallic compound, protein, steroid, organosilicon or nanomaterial
  - Not a high potency carcinogen:
    - (not aflatoxin-like, azoxy, N-nitroso or benzidine type compound)
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