A sector of CEPE aisbl

EuPIA European Printing Ink Association

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

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EFSA FCM Network

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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 10ppb for many substances

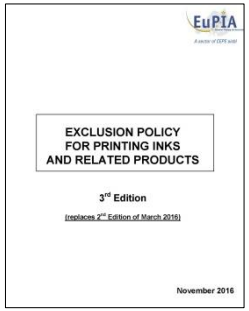
- Migration methods for non-plastic materials are not harmonised. Also some migration methods for plastic materials are unsuitable and give misleading results (Tenax @ 60 °C)

- 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

European Specific Measure for pFCM

- 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

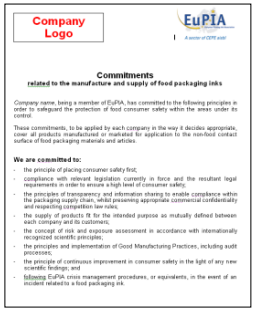

EXCLUSION POLICY
FOR PRINTING INKS
AND RELATED PRODUCTS

3rd Edition

(replaces 2nd Edition of March 2016)

November 2016

EuPIA Exclusion Policy


Company Logo

Commitments

related to the manufacture and supply of food packaging inks

EuPIA members Self Commitments


EuPIA Suitability List of Photo-Initiators for Low Migration UV Printing Inks and Varnishes – February 2013

EuPIA Suitability List of Photo-Initiators


Good Manufacturing Practice (GMP)
Printing Inks for Food Contact Materials

4th completely revised version

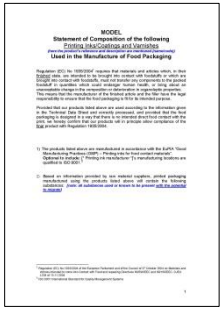
March 2016

Replaces the March 2009 version

EuPIA GMP


EuPIA Guidance for Risk Assessment of Non Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials

EuPIA Guidance for RA of NIAS/NLS


MODEL

Statement of Composition of the following

Printing ink(s)/Coatings and Varnishes

Used in the Manufacture of Food Packaging

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.

EuPIA Exclusion Policy

- **The Exclusion Policy uses the CLP classification rules as criteria**

GROUP A	GROUP B
Acute Toxicity Cat. 1 & 2 [H300, H310, H330]	
Acute Toxicity Cat. 3 (inhalation) [H331]	Acute Toxicity Cat. 3 (oral, dermal) [H301, H311]
Carcinogen or Mutagen Cat. 1A & 1B [H350, H340]	
Toxic to Reproduction Cat. 1A & 1B [H360] *(non-threshold substances)*	Toxic to Reproduction Cat. 1A & 1B [H360] *(if threshold exists)*
STOT Single Exposure Cat. 1 [H370]	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.

Step 2: Raw Material Selection

- **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

Step 3: Risk Assessment - Hazard

- 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:

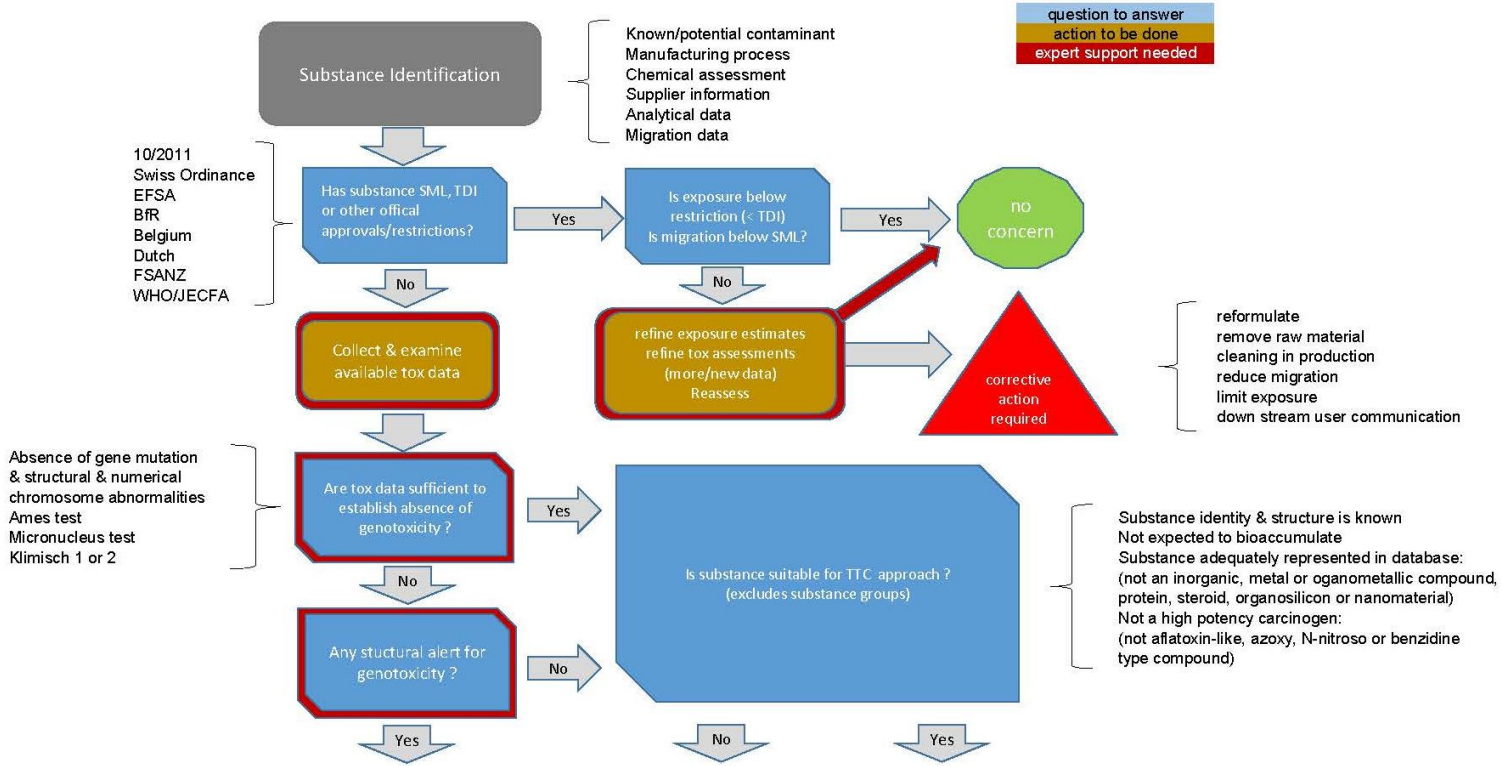
1. Fully evaluated substances
   - SML values from Union list, Swiss Ordinance or evaluations of MS authorities
2. Self derived TDI or SML values based on literature Tox data (for example REACH)
   - Derived from NOAEL, $DNEL^{long\ term\ oral\text{-}general\ population}$, TDI Data
   - Studies must 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

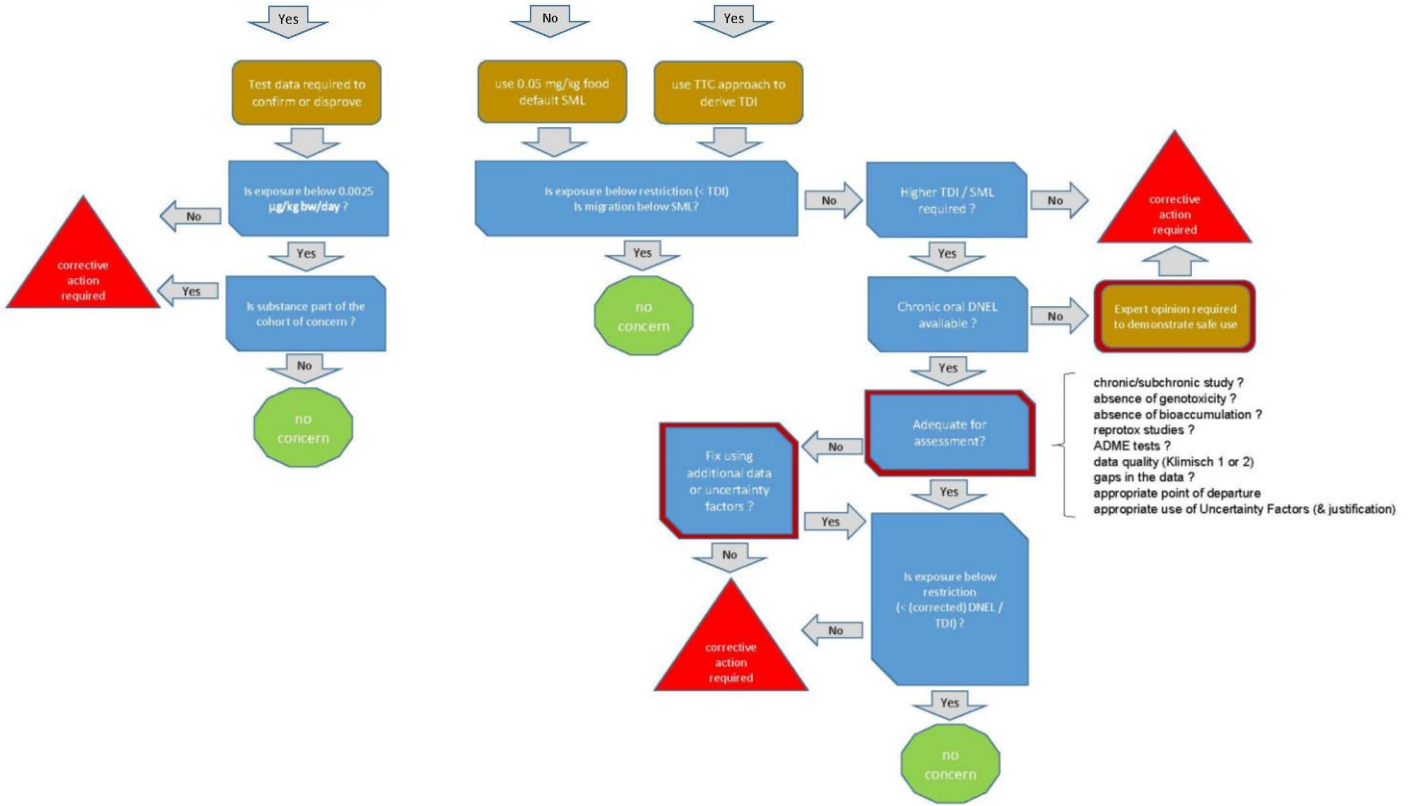
- **Exposure Identification**

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



NIAS/NLS Risk Assessment, pt. II



Thank You!

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