

# Update on European Printing Ink Regulations – Compliance of Additives and Raw Materials

## 欧洲油墨法规更新 – 添加剂和原料的合规

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# One Market – One Legislation

# 同一个市场 – 同一个法规



# EU Legislative Overview

## 欧盟法规概况



**Framework Regulation (EC) No 1935/2004**  
框架法规1935/2004

**GMP Regulation (EC) No 2023/2006**

### Materials specific Measures

### Substance specific Measures

**Regenerated Cellulose**  
2007/42/EC

**Ceramics**  
84/500/E  
EC

**A & I materials**  
(EC) 450/2009

**Plastics Regulation**  
(EU) No 10/2011

**Reg.1895/2005**  
BADGE/NOGE

**Recycled Plastics**  
(EC) No 282/2008  
(amendment in preparation)

**Printed FCM**  
(in preparation,  
but delayed延迟)

**Dir. 93/11/EC**  
Nitrosamines

European  
Commission

**Paper & Board**  
(DE, NL,IT, FR,  
CH)

**Coatings**  
(DE, NL,IT,  
ES, BE)

**Adhesives**  
(DE, ES,IT)

**Printing inks**  
(CH, DE on-  
hold)

**Silicones**  
(DE, F, ES,  
CH, NL, IT)

**Rubbers**  
(NL,DE,ES,  
FR)

Member  
States

**Glass, Wood, Cork, Textile, Metal, Ion  
Exchange Resins, Waxes**

# Global Food Contact Requirements

## 全球食品接触法规基本要求

- **General** global requirement: Substances which may migrate into food must not endanger human health  
基本要求：迁移到食品中的物质水平不应危害人体健康
- **EU: Framework Regulation (EC) No 1935/2004, Art.3**  
欧盟：框架法规(EC) No 1935/2004, 章节3
- **US/FDA: Food, Drug and Cosmetics Act, Sec. 402**  
美国/FDA：联邦食品、药品和化妆品法，第402节
- **China: Standard GB4806.1 & GB9685-2016, Art. 3.1**  
中国：国标GB4806.1 & GB9685-2016, 章节3.1



# Good Manufacturing Practice 良好生产规范 (GMP)

## Commission Regulation (EC) No 2013/2006

29.12.2006

EN

Official Journal of the European Union

L 384/75

附录：对应用于材料和制品非食品接触面的印刷油墨的操作要求

ANNEX

COMMISSION REGULATION (EC) No 2013/2006  
of 22 December 2006

on good manufacturing practice for materials and articles intended to come into contact with food  
(Text with EEA relevance)

### Detailed rules on good manufacturing practice

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.

3. The printed surfaces shall not come into direct contact with food.

# Risk Assessment Steps

## 风险评估步骤

### Risk Assessment of NIAS e.g. Impurities, Reaction- and Degradation Products

对非有意添加物的风险评估，如：杂质、反应产物和降解产物

- **Migration** into food evaluation 迁移评估  
Worst case calculation, if not OK experimental testing needed
- **Toxicology** assessment of migrants regarding CMR criteria and 毒理学评估
- **Derive** where applicable Tolerable Daily Intake (TDI) threshold 可推导的每日允许摄入量阈值
- **Verify** restrictions set by Authorities e.g. Primary Aromatic Amines (PAA) 验证官方设定的限制
- **Conclude** on tolerable migration into food 总结可接受的迁移量
- **File** Risk Assessment as Supporting Document (SD) 将风险评估存档作为支持文件



# The Balance of Substances

## 物质评估的天平（权衡）



IAS [PL]  
EFSA Risk Assessment  
EFSA风险评估

NLS & NIAS [SD]  
INDUSTRY Risk Assessment  
行业风险评估

# Toxicological Assessment

## 毒理学评估

### General approach to determine the dietary exposure limits for substances:

判断物质膳食暴露限值的途径：

- Determination of a TDI based on toxicological studies performed on the substance (additives), for NIAS structurally similar substance (read across) can be helpful in particular when their stability is not given or synthesis is not possible.

基于对该物质（添加剂）进行的毒理学研究确定一个TDI，对于NIAS结构相似的物质（交叉参照）可能会有所帮助，特别是当它们没有给出稳定性或无法合成时。

- If no substance-specific tox data are available, use the Threshold of Toxicological Concern (TTC) concept functions as a basis for assessment (unless exclusion criteria prevent the use of TTC).

如果没有可用的特定物质的毒理学数据，则使用毒理学关注阈值（TTC）概念函数作为评估的基础（除非排除标准阻止使用TTC）。



# Example Using the Threshold of Toxicology Concern (TTC)

## TTC使用案例

- Non-intentionally added substances (NIAS) with negative genotoxic test results assigned to Cramer Class III with max. TTC exposure limit, and  
具有阴性遗传毒性测试结果的NIAS分配给Cramer III类，最大值为TTC暴露限值
- **In accordance to EFSA** publication about recent developments in the risk assessment (EFSA Journal 2016;14(1):4357, 28 pp. doi:10.2903/j.efsa.2016.4357)  
根据EFSA发布的风险评估的最新进展

Type of TTC	TTC Value µg/kg b.w./day	TTC Value µg/60 kg/day
<b>Genotoxic Structural Alert*</b>	0.0025	0.15
<b>Non Genotoxic**</b>	<b>Cramer Class III</b>	1.5
	<b>Cramer Class I</b>	30

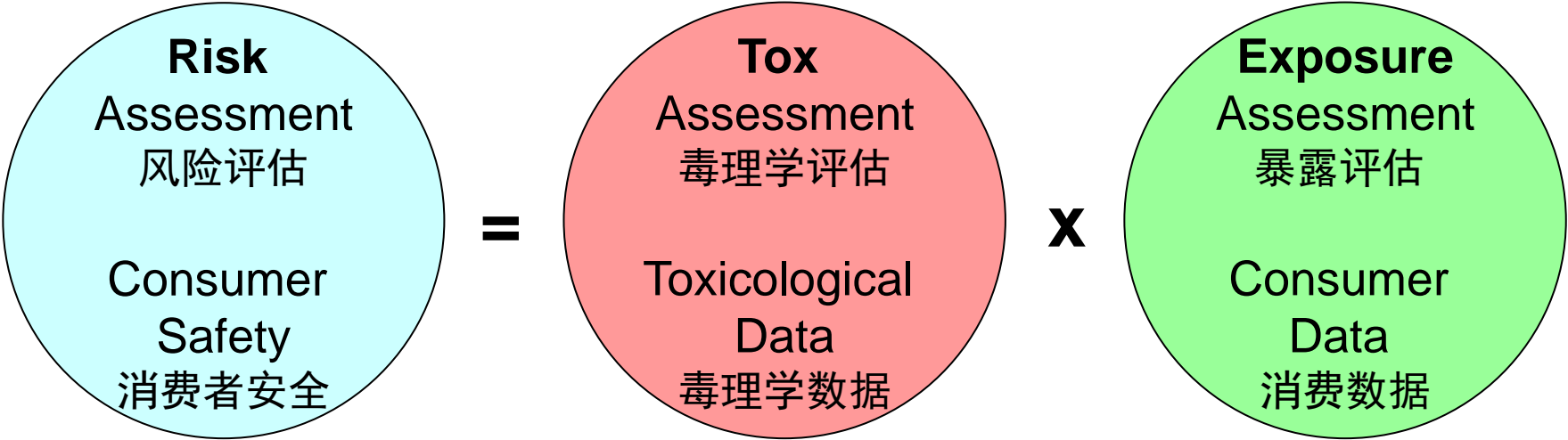
\* Default value

\*\* Class specific values

EFSA = European Food Safety Authority

# Risk Assessment Principle

## 风险评估原则



# EU Food Consumption Data

## 欧盟食品消耗量数据

### The EFSA Comprehensive European Food Consumption Database

Information on food consumption across the European Union (EU)

based on national food consumption surveys 数据库信息基于欧盟成员国食品消耗调查



efsa  
European Food Safety Authority

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- Chemical residues
- Compendium of Botanicals
- Standardisation
- How to assess data

### The EFSA Comprehensive European Food Consumption Database

The Comprehensive Food Consumption Database is a source of information on food consumption across the European Union (EU). It contains detailed data for a number of EU countries. The database plays a key role in the evaluation of the risks related to possible hazards in food in the EU and allows estimates of consumers' exposure to such hazards, a fundamental step in EFSA's risk assessment work. The database is also relevant to other fields of EFSA's work, such as the assessment of nutrient intakes of the EU population.

- [Guidance for the use of the EFSA Comprehensive European Food Consumption Database](#)

EFSA used its food classification system 'FoodEx' to categorise all foods and beverages included in the Comprehensive Database.

- [Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database](#)

**See also**

- [The EFSA DWH access rules](#)

<https://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

# Cefic-FCA Risk Assessment Guidelines

## Cefic-FCA 风险评估指南



### *FCA Guidelines on*

**Risk Assessment of non-listed substances (NLS) and  
non-intentionally added substances (NIAS) under the  
requirements of Article 3 of the Framework**

**Regulation (EC) 1935/2004**

**Version 2.0**

**September 2018**

**To help manufacturers and downstream users of  
food contact substances to fulfill the requirements  
of Article 3 of the Framework Regulation 1935/2004**

**帮助食品接触物质的制造商和下游用户满足框架法规  
1935/2004第3章的要求**

# Printed Packaging Value Chain

## 油墨印刷包装产业链

### Printing Ink Ingredients

#### 油墨组分

- Binders
  - polyacrylates
  - polyurethanes
  - nitrocellulose...
- Additives
  - Dispersants
  - Photo-stabilizers...
- Photo-initiators
- Colorants
- Solvents
  - Ethylacetate, water...

### Printing Ink Types

#### 油墨类型

- Liquid
  - Solvent based
  - Water based
  - Energy cured
- Paste, Oil based
  - Web-fed
  - Sheet-fed
  - Energy cured

### Printing Technology &

#### Machines 印刷技术&设备

- Flexo
- Offset
- Gravure
- Screen
- Digital

### Substrates, Packaging

#### Materials 基材、包装材料

- Paper&board
- Plastic
- Metal
- Glass...

### Packaging & Food Types

#### 包装 & 食品类型

- Flexible
  - Paper, plastic bags
- Rigid
  - Boxes, bottles...

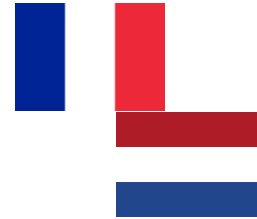
# European Regulatory Landscape of Printing Inks

## 欧洲油墨法规一览



### EU

- Regulation (EC) 1935/2004
- Regulation (EC) 2023/2006
- CoE Res AP(2005) 2, out of date
- pFCM Measure: on-hold



### F, NL

Colorants

- Brochure No 1227
- Warenwet Ch. II,X, XI



### GER

- Ordinance-Draft 2016  
on-hold
- BfR Submission & Approval



### CH

- **Ordinance** Annex 10,  
Positive List **Update**  
In collaboration with BfR



### Associations

- e.g. EuPIA Guideline

### Brand Owners

- e.g. Guidelines

# Swiss Ordinance SR 817.023.21

## 瑞士油墨法规



- **Positive list A, B in Annex 10 + SML read across plastic list Annex 2 正面清单**
  - ▶ **Five categories:** Monomers, Additives, Photoinitiators, Colorants, Solvents  
单体、添加剂、光引发剂、着色剂和溶剂
  - ▶ **NIAS** risk self-assessment required  
NIAS需进行自我风险评估
- **Application 应用**
  - ▶ Indirect food contact 非直接接触食品
- **Update 更新**
  - ▶ Non-evaluated substances & new entries 未评估物质和新物质

# German Draft of Printing Inks Ordinance

## 德国油墨法规草案



### ■ **Positive List** of Monomers, Additives, Photoinitiators, Colorants, Solvents 正面清单

- ▶ **Non-listed** substances allowed in **indirect food contact** if migration < **DL** = 0.01 mg/kg
- ▶ **Exempted** are substances applied on **absolute barrier** e.g. metal cans

### ■ **Application** 应用

- ▶ Indirect food contact e.g. surface printing 非直接接触食品，如表面印刷
- ▶ **Direct** food contact 直接接触食品
  - *Intentional* e.g. paper bags 有意接触，如纸袋
  - *Non-intentional* but foreseeable e.g. napkins 非有意但预期有接触，如纸巾

### ■ **Update** 更新

- ▶ No, currently on-hold 无



# Regulation Framework

## 法规框架



- **Framework Regulation** 1935/2004 e.g. **Art. 3** not to endanger human health etc.
- **GMP** Regulation 2023/2006 for FCM incl. application of printing inks, Set-Off (ANNEX)
- **Plastic Regulation** 10/2011, use of SML values in Annex 1,
- **National** Regulation GER, NL, F - **Colorants Purity**: e.g. heavy metals, PAAs...
- Swiss Ordinance
  - Annex 10, updates and new entries on a regular scheme

# BfR IX - Purity Requirements for Colorants

## BfR建议IX – 着色剂的纯度要求



- The detection limit is 0.01 mg/kg and applies to the sum of the released primary aromatic amines  
检出限为0.01 mg/kg适用于所释放的初级芳香胺总和
- Primary aromatic amines classified as carcinogens in classes 1A and 1B of the CLP Regulation (EC) 1272/2008 may not be released referred to the single substance with a detection limit of 0.002 mg/kg food or food simulant  
不得释放根据CLP法规(EC) 1272/2008被分类为致癌性类别1A和1B的PAAs，检出限为0.002 mg / kg食品或食品模拟物的单个物质



We create chemistry