Printing Inks for Flexible Food Packaging: U.S. and EU Regulatory Considerations

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A Preliminary Word…

Legal challenges...

Regulatory trends regarding chemicals
Different legal requirements regarding use of printing inks in food packaging in the United States and Europe
• No single list to look at
• No single safety standard
• No single set of migration conditions.

Marketing challenges...

Brand owners and their products under tremendous public scrutiny re chemicals
Agenda: Food Contact Compliance for Printing Inks

- U.S. FDA Regulation
- Harmonized EU Legislation
  - GMP Regulation (2023/2006)
- EU Member State Legislation

- No single FDA or EU-wide regulation or list specifically clears “inks” used in food packaging
- In U.S., need to assess components (colorants, binders, carriers, solvents) on a case-by-case basis
- In Europe, need to assess components on a nation-by-nation basis
FDA Overview

U.S. FDA authorized to prevent adulteration of food

Food packaging adulterates food

• If it makes the food unsafe;
• If it makes the food unfit for consumption (for example, by imparting an unacceptable taste or odor); or
• If the packaging component qualifies as a food additive, but does not have premarket clearance by FDA
FDA: General Principles

- FDA has authority to require premarket clearance for printing ink components that are “food additives”
  
  • While substrates (e.g., paper/board, plastics) are covered by various FDA provisions, no one regulation clears printing inks

  • Inks may be used based on available exemptions (e.g., “no migration,” General Recognition of Safety)

- Must meet suitable purity standard of 21 CFR §174.5 (FDA’s GMP regulation)
Establishing Suitable FDA Status

- The critical questions: Composition and intended use of the product?
  - Composition of the product?
    - Chemical identity
    - Formulated mixture
    - Adjuvants
  - What is its intended use?
    - Food types
    - Temperatures
    - Duration of contact
Evaluating FDA Compliance – Our Approach

If it is not cleared and no exemptions apply, then an FCN (or possibly food additive petition) must be filed.
FDA: Food Additive Regulations

- Some applicable FDA food additive regulations for printing ink components:
  - 21 CFR §178.3297 (“Colorants for polymers”)
  - 21 CFR §176.170 (“Components of paper and paperboard in contact with aqueous and fatty foods”)
  - 21 CFR §175.320 (“Resinous and polymeric coatings for polyolefin films”)
  - Stand-alone regulations, e.g., 21 CFR §177.1520 (“Olefin polymers”)

- Need to consider limits on clearances
  - Food types, temperatures, and use levels
Other Options for Establishing FDA Status

- TOR exemption letter from FDA
- Applicable Food Contact Notification issued by FDA
- No migration/functional barrier (Self-determination)
- GRAS position (based on 21 CFR listings or self-determination)
FDA: Migration Considerations

- Is there a reasonable expectation that ink components could migrate to food?

- Potential for migration depends on:
  - Molecular weight and concentration of ink component
  - Volatility
  - Type and thickness of material(s) separating food from ink
  - Duration and temperature of exposure
  - Type of food
Functional Barrier Concept

- Ink manufacturers rely on customers/end users to demonstrate use of effective barrier to prevent ink migration to food

- Assessment based on:
  - Theoretical calculations
  - Migration testing
  - Use of intervening “absolute” barrier layer (e.g., aluminum foil)

- Safety of ink components relevant to Limits of Detection
FDA: Functional Barrier

- FDA considers the following to be functional barriers for all possible migrants:
  - Aluminum foil
  - PET film 1 mil (25 µm) thick for room temperature applications
- Polyolefins **not** considered all-purpose functional barrier
Addressing Offset/Set-off

- Occurs when rolled or stacked packaging material results in transfer of ink from printed exterior of package to the food contact side during storage and handling of packaging material.

- GMP issue

- Monitoring and assessment needed to avoid contamination.
FDA: Practical Issues

- Ink formulations tend to be complex, with many layers of suppliers and sub-suppliers
- Most ink formulations are not composed entirely of cleared components
- Many FDA assurance statements for inks simply require use of a functional barrier
  - Determined by user of ink
  - But user typically lacks sufficient information on ink to assess potential migration and toxicity of ink components
EU: Harmonized Legislation

- No legislation specifically regulating printing inks at the EU level
- Framework Regulation and GMP requirement apply to all FCMs
  - Specific rules for printing inks applied on non-food-contact side of FCMs in GMP Reg.
    - Must not transfer through the substrate
    - Must not be transferred at unsafe levels when stacked or rolled (offset)

- Plastics Regulation applies to printed plastic food contact FCMs
  - Printing ink components NOT subject to positive list
EU Framework Regulation – Article 3

Food-contact materials and articles

• Must comply with GMP
• Must not transfer constituents to food that could endanger human health
• Must not contribute an unacceptable change in the composition of the food
• Must not deteriorate the organoleptic characteristics of the food
EU GMP Regulation (2023/2006)

- Applies to all food contact materials at all stages of production
- Must implement quality assurance system and maintain supporting documentation
- Provides specific rules for printing inks applied on non-food contact side of M&A
  - Inks must not transfer at unsafe levels:
    - Through substrate to food contact surface
    - Must not be transferred at unsafe levels when stacked or rolled
EU Plastics Regulation (10/2011)

- Applies to plastics (with or without printing inks) and to multi-material multilayers
- Art. 2.3: Plastics Regulation does *not* include a positive list for components of printing inks
  - Printing inks may be comprised of substances other than those authorized by the Plastics Regulation
- But, final printed plastics material/article must meet applicable specific migration limits (SMLs) and overall migration limits (OMLs)
Swiss Printing Inks Ordinance

- Current reference in the EU (although not an EU Member State)
- RS 817.023.21 of May 1, 2017 sets specific requirements for food-contact FCMs
- Scope -- The provisions on inks do not apply if
  - The packaging ink layer is in direct contact with food
  - Migration into food of ink substances is rendered impossible
  - Set off or transfer via a gas phase can be excluded

- Positive lists for components of:
  - Printing inks (Annex 10)
Swiss Printing Inks Ordinance

- **List of permitted substances**: Printing inks may be manufactured only using substances mentioned in Annex 2 and Annex 10:
  - Annex 2 (plastics)
  - Annex 10 provides the following lists:
    I. **Binders** (monomers)
    II. **Colorants and pigments**
    III. **Solvents** (including energy curing monomers)
    IV. **Additives** (does not include those used in the preparation of pigments and aids to polymerization)
    V. **Photoinitiators**

=> Subject to the conditions specified therein
Swiss Printing Inks Ordinance – Positive List

- Annex 10: the lists are divided into two parts
  - **Part A: Evaluated substances**
  - **Part B: Non-evaluated substances**; these are permitted provided that
    - No transfer into food or food simulants may be detected; detection limit of 0.01 mg/kg
    - New: Not carcinogenic, mutagenic, or toxic to reproduction

- New for Part A and Part B: substances deliberately engineered to nanoform must be listed as such
  - New: Colorants and pigments containing nanoparticles are authorized if it can be ensured that there is no migration of nanoparticles to food
Draft German Printing Inks Ordinance

- Notified to the European Commission on July 7, 2016 (Notification no. 2016/333/D)
  - Detailed opinions (i.e. objections) by Austria, Finland, France, Greece, Italy, the Netherlands, Spain and the United Kingdom
    - The Commission, Denmark and Sweden issued comments
  - Germany did not take steps to adopt
Draft Harmonized Measure on Printed FCMs

Why?

- Draft German Printing Inks Ordinance
  – Objections from many Member States

- European Parliament Resolution calling on Commission (“EC”) to harmonize several areas including printing inks

- EC’s Joint Research Centre study highlighting levels of primary aromatic amines in printed paper napkins at concentrations that “are relevant for monitoring”

- Lack of understanding of mutual recognition principle
Printed FCMs – EC Proposed Approach

- **EC wants to move away from positive list system**

- **Certification of compliance by “designated bodies” (DB)**
  - of intermediate products

- **AND**

- of final articles

- **Centralized database** of assessed substances and/or supporting documentation

- **Control of the work of designated bodies by enforcement authorities**
Printed FCM – EC Proposed Approach

- If certification is systematically required for intermediate products and for final articles
  ⇒ New system would be based on presumption of non-compliance of FCM unless certificate has been granted by DB
  ⇒ End of self-assessment of compliance and traditional Declaration of Compliance
Is the Approach Enforceable?

- What if differing interpretations from DBs for the same/similar products?
- What if something goes wrong after marketing of a certified product?
  - Would the company benefiting from the certificate be the one responsible, or should it be the DB?
Other Issues and Possible Solutions

- How can printed FCMs freely circulate in the EU if substrates (e.g., paper and paperboard, rubber) are not harmonized?
- EC approach based on view that industry is not taking adequate steps to ensure compliance
  - BUT shortcomings with current system/legislation; need for
    - Guidance on how to conduct risk assessments
    - Rules on how to handle confidential business information
    - Training for business operators and Member State enforcement authorities
Practical Takeaways

- Ink formulations complex, with many layers of suppliers and sub-suppliers
- Most ink formulations are not comprised entirely of listed components
- Many assurance statements for inks simply require use of a functional barrier
  - Compliance falls on food companies
  - More often determined by user of ink
  - However, user typically lacks sufficient information on ink to assess potential migration and toxicity of ink components
- Brand owners with far more rigorous
Do you have assurance letters from each of your suppliers?

Are they up to date?

Are they periodically reviewed?

Must assess status of each and every component that may migrate to food

End use dependent - are your customers’ uses covered?

Best Practices: Vet Your Suppliers
Best Practices: GMP

1. Establish testing program to assure compliance of product with regulatory requirements and internal specifications

2. Document test results

3. Determine appropriate period testing
Best Practices: Providing Customer Assurance

- Your Guarantees and Declarations of Compliance
  - Limit personnel who may issue letters
  - Ensure regulatory group is involved in every change of formulation you supply
  - Can rely on customer letters in issuing your own certifications
So You Want to Supply in the Food Packaging World...

- Know your company’s tolerance for pain
- In U.S.?
  - Watch for activity at state level: chemical restrictions
  - Simple rule of thumb: If it migrates, must have FDA clearance...
- In EU?
  - Comply with specific national legislation where applicable
  - Otherwise, printing inks must meet general harmonized requirements
- Safety and GMP are key (but in and of themselves, insufficient!)
THANK YOU

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