Low Migration in Food Packaging

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Presentation Content

- Regulations impacting packaging
- FDA brief history
- FDA food packaging regulation
- European situation
- US status
- Why use & What is low migration technology
- Testing
The good old days
Typical Packaging
Brief History of the FDA

- Traced back to 1820 when 11 physicians produced the US Pharmacopeia
- President Lincoln started the Bureau of Chemistry in 1862
- 1906 saw the first truly food related law pass when the Food and Drugs Act was enacted
- Labeling was regulated in 1913 with the Gould Amendment
- In 1930 the organization received its current name – The Food and Drug Administration
Key FDA regulations

- Delaney committee establishment of GRAS list – 1958
  - Substances Generally Regarded as Safe
  - Food additive petition
  - TOR – threshold of regulation (*di minimis*)

- Food and Drug Modernization Act – 1997
  - Established the FCN process
Definition:
“any substance the intended use of which results, or may reasonably be expected to result… in its becoming a component or otherwise affecting the characteristics of any food” is a food additive.

Level:
Based on the Ramsey proposal and the later Monsanto v. Kennedy case, a general level of 50 ppb or less is acceptable if the substance is not a carcinogen, reproductive toxin, mutagen or toxic at a level of 40 ppm or less.
Commercial Pressures - Brand owner input

- Understanding liability better and brand damage potential
  - Kellogg’s liner odor

- Going global on their view of what they need – Nestle, Kellogg, P&G

- Developing own print guidelines
  - Already becoming too complex for packaging supply chain to manage
  - E.g. Nestle, Tetrapak, Kellogg’s, Sony, Phillips, Lego, Lidl, M&S…..

- Switching to low migration solutions for high risk applications
Why is chemical migration important

Evidence of mineral oil migration from transit packaging identified in 2010. **RECALL:** 28MM cereal cartons
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<th>HOW DOES MIGRATION OCCUR?</th>
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| 1. Physical Migration | PENETRATION MIGRATION  
Migration from the printed side through the substrate onto the unprinted side. |
|   | Penetration through the substrate |
| 2. Physical Migration | CONTACT MIGRATION  
Migration from the printed side to the unprinted side of another sheet in a stack or roll. |
|   | “Set-off” transfer onto the reverse side in the stack |
| 3. Gas Phase Migration | EVAPORATION MIGRATION  
Migration due to the evaporation of volatile materials by heating (e.g. cooking, baking, or boiling frozen products in their original packaging). |
|   | Vapour phase transfer |
| 4. Gas Phase Migration | CONDENSATION MIGRATION  
Migration through steam distillation during cooking, baking or sterilisation. |
|   | Condensation extraction |
Sources of migratable materials
Baby milk scare widens in Europe

Swiss-based food giant Nestle has ordered the recall of baby milk from France, Spain, Portugal and Italy after tests suggested chemical contamination.

Police in Italy, the largest market of the four, have begun seizing 30m litres of the baby milk from shops and depots.

The alarm was raised after traces of a chemical involved in the printing process were found in samples in Italy.

Nestle denies the chemical poses a risk to health but has recalled the cartons, with an expiry date of September 2006.

The scare began in June when a sample of liquid baby milk produced by Nestle showed traces of isopropyl thioxanthone, a photographic chemical known by the initials ITX.
European Response

- Several corporations moved on their own to develop lists of positive and negative materials – Nestle guidance list
- Several governments moved to implement clearer sensitive packaging guidance documents – Swiss Ordinance

- Believed that the German effort will become the standard for the European Union

- General guidance is very similar to FDA recommended position unless specified SML is higher
Current US situation

- Ideal is no migration: no exposure = no risk

- Migration <0.5 ppb, safe by TOR unless carcinogen, reproductive toxin or poison

- Migration <10 to 20 ppb, likely not a concern

- Migration < 50 ppb, general FDA guideline

- Migration > 50 ppb, need toxicity data
Materials of Concern - Migration from Packaging

- Mineral oils
- Photo-initiators from UV ink and coating systems
- Heavy Metals
- Phthalates
- Bisphenol A
- Benzophenone and derivatives
- Paraffin waxes
- Aldehydes produced from ink oxidation/drying reactions
- Benzene from wash-up solvents
- Residual styrene from aqueous coatings
- Other solvents
Design Stage

- Raw materials for LM technology are carefully selected before becoming a part of the formulation
  - Organoleptic tests
  - Migration tests
  - Compliance with legal requirements
  - Vegetable chemistry (refined), no hydrocarbons

- Low migration printing inks shall not contribute to the balance of “safe packaging” industry

- Formulations are sometimes shared with third parties under non-disclosure to help brand owners understand chemical relationships
Sun Chemical adopted parts of the so-called Hazard Analysis and Critical Control Point (HACCP) principles

- HACCP is realized in the food and pharmaceutical industry.
- Food packaging converters may be certified according to HACCP

Sun Chemical GMP (Good Manufacturing Process) guidelines for the production of food packaging inks established by EuPIA

- Classic printing inks are never produced inside this plant
- Floor and equipment cleaning with approved solvents only
Incoming Raw Material Control

- All raw materials are provided with supplier COC
- Pre-sampling of raw materials is required prior to delivery to the plant
- All materials are checked for compliance to specification via GC MS
- Raw material quantitative information for every batch is stored on the SAP mainframe for traceability
Extraction Cell
Decision tree for inks/coatings to be used

Designing Packaging with Certainty – Route Finder

**PACKAGE DESIGN CONCEPT STAGE**

**FOOD**
- **Primary Packaging**
  - Always select Low Migration inks and coatings

**NON FOOD**
- **Ensure compliance to applicable regulations e.g. Toys, Heavy Metals, etc.**

**STEP 1**
- **Primary Inner Wrap**
  - Is Functional or Absolute Barrier
  - Testing confirms no risk of migration, revert to low tint and odor standard inks and coatings

**STEP 2**
- **Primary Outer Wrap Packaging**
  - Primary Inner Wrap has no barrier properties or barrier performance is unknown
  - Test pack for migration performance and perform risk assessment

**STEP 3**
- **Confirmed migration risk is above regulatory limits**
  - Use Low Migration Products

**STEP 4**
- **Lowest Risk Option**
  - Select Low Migration inks and Coatings

**STEP 5**
- **PRODUCT RECOMMENDATION**
  - If no migration risk by another means
    - SELECT: Low tint and odor standard inks and coatings

  - If film or foil substrate
    - SELECT: SunCure FLM, SunCure QLM or SunBeam ELM and Low Migration Coatings

  - If paper or cartonboard substrate
    - SELECT: SunCure FLM, SunCure QLM, SunCure QLM, SunBeam ELM, SunPak FSP, SunPak LMO and Low Migration Coatings

  - If film or foil substrate
    - SELECT: SunCure FLM or SunBeam ELM and Low Migration Coatings

  - If paper or cartonboard substrate
    - SELECT: SunCure FLM, SunCure QLM, SunBeam ELM, SunPak LMO and Low Migration Coatings

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  - If paper or cartonboard substrate
    - SELECT: SunCure FLM, SunBeam ELM, SunPak LMO and Low Migration Coatings

  - No Migration Issue
    - SELECT: Standard inks and coatings
Low migration printing is not just about ink!

4 Step Model to designing packaging with certainty

- Pre-Press & Pack Design
- Selection of materials
- Printing Equipment & Management
- Press Room, Handling, Transport & Storage
Prop 65 – intended to protect the water from harmful chemicals and inform citizens about them.
- Unfortunately no \textit{de minimis} value
- Many people do not understand
- Common food items contain materials on list
  - Carrots, chocolate, beer…

Some customers “demand” that inks be Prop 65 free
Coke, Pepsi change formulas to avoid cancer warning label

9 hrs ago

Coke and Pepsi are making some changes to their formula to avoid having their cans slapped with a cancer warning label. The companies directed their suppliers to reduce the level of the chemical 4-methylimidazole, which is a component of the caramel coloring and can be found in trace amounts in the soda. The change comes following a California law that demands drinks with a certain level of carcinogens display a warning, and while scientists say there are no immediate health concerns associated with the product (despite a few Twitter users freaking out), the two companies are changing the way they make their coloring to comply. Fortunately, the drinks will still be packed with all the sugar and empty calories you can handle.
Approach needed

- Communication – up and down supply chain
- Understanding – what is truly needed
- Control – of the process
- Material selection – start with the correct components
- Testing – where do we stand
Thank You

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