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FDA Regulation of Printing Inks for Manufacturers and Suppliers

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FDA Regulation: General Principles

- Federal Food, Drug, and Cosmetics Act, *inter alia*, prohibits the adulteration of food
- Food packaging may adulterate food if--
  - The packaging makes the food unsafe
  - The packaging makes the food unfit for consumption (e.g., unacceptable taste/odor)
  - The packaging materials qualify as *food additives*, but do not have premarket clearance by FDA

Food Additive Definition

- A substance which, when used as intended, is reasonably expected to become a component of food, except GRAS and prior sanctioned substances, among others
- Food additives must be the subject of a regulation or Food Contact Notification (FCN)

FDA Regulation: General Principles

- FDA has authority to require premarket clearance for printing ink components that are “food additives”
  - Ink components treated like any other packaging component
  - HOWEVER, no single FDA regulation clears printing inks
  - May be used based on available exemptions (*e.g.*, “no migration,” General Recognition of Safety)
- Must be suitably pure for its use (21 CFR §174.5)

FDA Food Additive Regulations

- Certain components of inks might be found in FDA's food additive regulations:
  - Stand-alone polymer regulations, *e.g.*, 21 CFR §177.1520 ("Olefin polymers")
  - Stand-alone additive regulations, *e.g.*, § 178.3620 ("Mineral oil")
- Need to consider limits on clearances
  - Nature of use, food types, temperatures, and use levels

Other Routes for Establishing FDA Status

- Prior sanction
- ToR exemption Letter
- Applicable FCN
- No migration/functional barrier
- GRAS position (based on toxicity data, or low dietary exposure)

Functional Barriers

- Inks may be marketed based on existence of a functional barrier preventing migration of ink components to food
  - FDA considers the following to be functional barriers for all possible migrants:
    - Aluminum foil
    - PET 1 mil (25 µm) thick for *room temperature* applications
  - Polyolefins are <u>not</u> considered all-purpose functional barriers

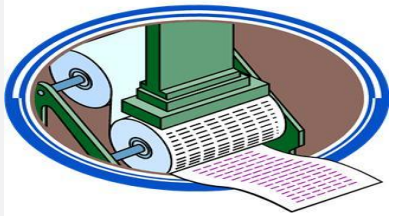
Functional Barrier (con't)

The existence of a functional barrier depends upon

- The composition and thickness of the barrier material
- The physical properties of the substance the barrier is intended block (*e.g.*, molecular weight, volitility, polarity)
- Temperature and duration of exposure
- Type of food (fatty, aqueous, acidic)

Offset Issues

- 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 as technically and economically feasible
  - Must not present an unreasonable risk of harm

FDA Regulation: Questions

- What impact does the packaging structure have on FDA compliance of inks (*e.g.*, direct printing on single or multi-layer, printing on labels, printing on paper where liner is present)
- Does packaging structure ever achieve a point where ANY ink would be compliant? If not, what baseline evaluation would be needed?

Food Safety Modernization Act (FSMA)

- Signed into law in January, 2011
  - Peanut Corporation of America - deadly salmonella outbreak in 2008 (9 deaths; 700+ illnesses)
  - Other high profile food recalls
- FSMA gives FDA greater authority to:
  - Prevent food safety problems (Title I)
  - Detect and respond to food safety problems (Title II)
  - Improve safety of imported food (Title III)

Title III: Safety of Imported Food

- Foreign supplier verification program (FSVP) Rulemaking
  - Final rule; 80 Fed. Reg. 74226 (Nov. 27, 2015)
  - Applies to food as defined in 201(f) FFDCA
  - Food *includes* "food additives" which *includes* food contact materials!!!
  - Effective January 26, 2016, but 18 months to comply (May 29, 2017)
- Voluntary qualified importer program (VQIP)
- Import certification
- Accreditation of third-party auditors

FSVP – Scope

- Impacts importers of food packaging materials and other FCSs that are *food additives*
  - Finished food contact articles (bottles, closures, etc.)
  - Preforms, resins, additives, stabilizers, etc.
- And, therefore, may include some printing inks or ink components

FSVP – Purpose

- Importers must implement FSVP to assure their foreign suppliers produce ‘food’ in compliance with:
  - Risk based preventive controls (HARPC) under Section 418
  - Produce safety provisions of Section 419
  - Adulteration provisions of Section 402
  - Misbranding provisions of Section 403(w) (allergen labeling)

FSVP – Five Requirements of Importers

(1) Hazard identification and analysis

(2) Foreign supplier approval based on that hazard analysis

(3) Foreign supplier verification that identified hazards are appropriately controlled by the supplier

(4) Corrective actions, as appropriate, to control hazards

(5) Recordkeeping of FSVP activities

** Must by conducted by a “Qualified Individual” **

FSVP – Partial Exemption

- Foreign supplier approval and verification steps NOT required if hazard analysis determines that there are no hazards associated with the ‘food’ that require a control to ensure safety
  - Not a complete exemption from FSVP
  - Hazard analysis by QI still needed, and records of same

FSVP: Questions

- Is it possible that all material suppliers to FDA compliant food packaging will have substantial new requirements under FSMA requiring us to register under FSVP?

THANK YOU!

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