



# Navigating FDA Regulations for Food Grade Packaging

March 25, 2010

**Pamela L. Langhorn, Partner**

Keller and Heckman LLP

1001 G Street, N.W.

Washington, DC 20001

202-434-4291

langhorn@khlaw.com

[www.khlaw.com](http://www.khlaw.com)

Washington, D.C. • Brussels • San Francisco • Shanghai

# Presentation Overview

---

- Basic Background on FDA Regulation
  - FDA Clearances
  - Exemptions and Exceptions
  - FCN Basics
  - Suitable Purity under 21 C.F.R. § 174.5
- Special issues to consider for ‘sustainable’ packaging
  - Renewable Sources
  - “Biodegradable” Packaging
  - Recycled Content
- Questions

# Background: FDA Authority

---

- U.S. Food and Drug Administration (FDA) has authority to prevent adulteration of food
- Food packaging may adulterate food if
  - The packaging makes the food unsafe;
  - The packaging makes the food unfit for consumption (for example, by imparting an unacceptable taste or odor); or
  - The packaging materials qualify as *food additives*, but do not have premarket clearance by FDA

# Background: '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 (§ 201(s))
- Food additives must be the subject of a regulation or Food Contact Notification (§ 409)

# Background: Premarket Clearance

---

- Existing FDA premarket clearances can be found in:
  - 21 C.F.R. Parts 175-186
    - General applicability
  - FDA's Inventory of Effective Food Contact Notifications (FCNs)
    - Can be relied on only by Notifier and its downstream customers
  - FDA's list of Threshold of Regulation exemptions
    - General applicability

# Background: Premarket Clearance

---

- Does the regulatory clearance apply to your use?
- Do any limitations on food type exist?
- Do any limitations on temperature exist?
- Are quantitative limitations of the applicable regulation met?
- Does the substance/article meet the applicable end-test requirements?

# Background: Exemptions/Exceptions

---

- Exemptions from the need for premarket approval by FDA stem primarily from ‘food additive’ definition
  - Only ‘food additives’ require premarket clearance
- Exemptions include:
  - “No migration” to food: a substance not reasonably expected to become a component of food is not a food additive
    - *Monsanto v. Kennedy*: FDA must find a substance migrates into food in more than insignificant amounts to consider it a food additive
    - “No” migration – 50 parts per billion (ppb), and sometimes less

# Background: Exemptions/Exceptions

---

- Exemptions (cont'd)
  - Generally recognized as safe (GRAS)
    - Some in regulations (Parts 182, 184, and 186)
    - Self-determination
  - Prior-sanctioned substances
    - Pre-1958 Approvals by FDA or USDA
    - Lehman List
    - Private Letters
    - Part 181



# Background: Exemptions/Exceptions

---

- Exemptions (cont'd)
  - “Basic resin” substances
    - Clearance of a basic polymer or resin subsumes clearance of the reaction control agents (*e.g.*, catalysts, initiators, chain terminating agents)
  - Housewares
    - Articles that are used by consumers, or in some circumstances, commercial food-service establishments, to prepare or serve food

# Background: FCN Basics

---

- Existing food additive regulations and threshold of regulation determinations remain valid, **but** no new food additive petitions for packaging materials except where FDA determines it is necessary
- Food-contact material can automatically be legally marketed unless FDA objects within 120 days of the FCN filing date
- Key components of FCN include:
  - Form 3480
  - Copies of relevant data/reports
  - Comprehensive Toxicology Profile
  - Environmental Assessment (if needed)

# Background: FCN Basics

---

- General data requirements:
  - Chemical identity/composition of FCS
  - Information on specifications
  - Manufacturing process
  - Information on impurities and breakdown products
  - Intended conditions of use
  - Intended technical effect
  - Migration data and reports
  - Estimation of dietary exposure
  - Relevant toxicity data
  - Environmental Assessment (sometimes)

# Background: Suitable Purity

---

What is suitable purity? 21 C.F.R. § 174.5

- Material must not be contaminated so as to cause food to be:
  - (1) Unsafe, or
  - (2) Unfit for consumption (taste or odor)
- Requirement applies even if all components are covered by food additive regulations or Food Contact Notifications

# Special Issues for 'Renewable' Sources

---

- Basic clearance issues
  - Does a specific clearance already exist?
    - If yes, does the material made from the 'renewable' source still meet the chemical description, specifications, etc.?
    - If not, consider exemptions
  - Is the material suitably pure (any new/unusual impurities)?
- If material is not covered by an existing clearance and does not qualify under an exemption, FCN is needed

# Special Issues for 'Biodegradable' Packaging

---

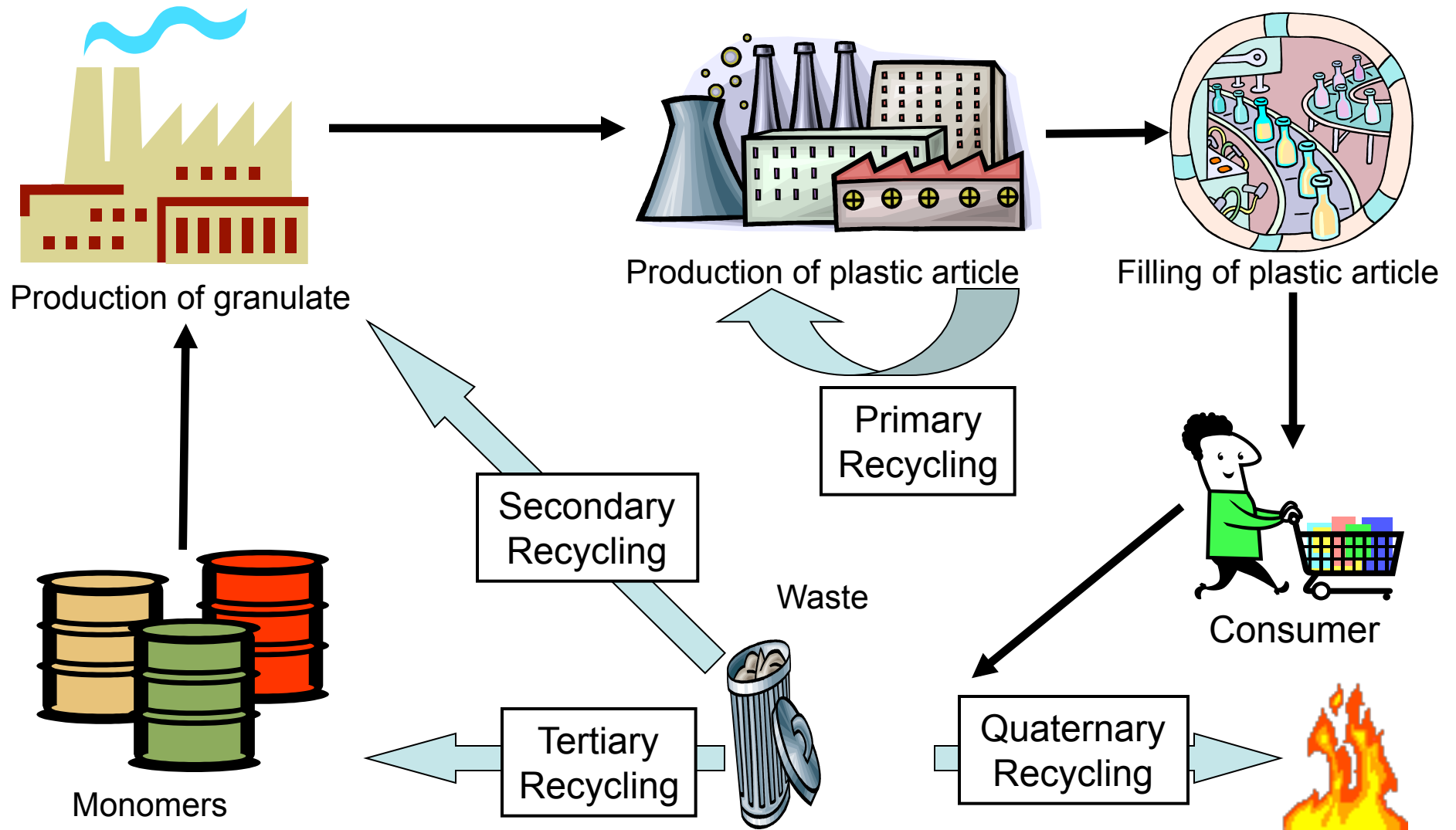
- Basic clearance issues apply
  - Substrate (plastic, paper, etc.) must have appropriate FDA status in the first instance
- What additives/mechanisms improve degradability?
  - These also require an appropriate FDA status
- Suitable purity: will degradation begin prior to consumption of packaged food?

# Special Issues for Recycled Content

---

- A few general considerations are relevant, regardless of specific substrate at issue
- In-plant scrap
  - Is the scrap material FDA food-contact compliant?
  - Suitable purity – does it introduce any new chemical or microbiological impurities?
- Post-consumer
  - Is the source material FDA compliant?
  - Suitable purity – does it introduce any new chemical or microbiological impurities?
    - If so, is there a mechanism in place to remove such contaminants?

# Special Issues: Recycled Plastics





# Special Issues: Recycled Plastics

---

- Chemical depolymerization (i.e., tertiary recycling)
  - Polymers produced from this process can be considered covered by applicable regulation for the virgin polymer, provided that polymer is suitably pure and otherwise meets regulatory specifications
  - FDA will issue letters of no objection, upon request
    - For PET and PEN, no data needed, as FDA has determined that tertiary recycling processes produce suitably pure polymers
    - For all other polymers, FDA will require supporting data

# Special Issues: Recycled Plastics

---

- Mechanical (secondary) recycling
  - Plastics produced from this process can be considered covered by the applicable regulation for the virgin polymer, provided the polymer is suitably pure and otherwise meets regulatory specifications
  - FDA will issue letters of no objection for plastics produced from a specific process; not required from a regulatory perspective

# Special Issues: Recycled Plastics

---

- Mechanical recycling (cont'd)
  - Must establish that process is sufficiently robust to ensure suitable purity
    - FDA recommends challenge testing
      - Involves spiking surrogates for classes of chemicals into polymer and then measuring them in finished plastic
      - Dietary exposure target is 0.5 ppb or less
    - FDA Guidance document:  
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm120762.htm>

# Special Issues: Recycled Paper

---

- 21 C.F.R. § 176.260 permits the use of pulp from reclaimed fiber
  - PROVIDED that it does not contain any poisonous or deleterious substances that migrate to food
  - Simply put, suitable purity is the standard
- Establishing suitable purity
  - Fundamentally different from plastic recycling
    - Involves washing of recycled fibers, but process is necessarily less severe than mechanical cleaning of plastics
    - Because process is not geared toward ‘cleaning’ the fibers, challenge testing does not make sense here

# Special Issues: Recycled Paper

---

- Establishing suitable purity (cont'd)
  - FDA has no official guidelines for testing recycled paper to establish suitable purity
  - Approaches commonly used by industry include source control, routine chemical contaminant testing, etc.
- FDA can (in principle) issue letters of no objection for recycled paper; not required from a regulatory perspective
  - Past: Very difficult to get LNO from FDA due to their insistence on challenge testing (we are aware of only one LNO)
  - Present: FDA has no official testing guidelines and is discouraging submissions
  - Future: ??

# Other Thoughts

---

- Reduction in packaging can also present unique challenges
- The purpose of packaging is to preserve the integrity of the packaged food
- Must be cautious not to reduce packaging to the point where the food is at risk of environmental contamination
  - Taste/odor issues
  - Migration from outer (secondary) packaging

# Conclusion

---

- Always start with basic FDA regulatory considerations – is the material cleared?
- Also consider unique suitable purity issues that may be presented by particular product
- Questions?



# Thank you!

**Pamela L. Langhorn**  
**Partner**

Keller and Heckman LLP

1001 G Street, N.W.

Washington, DC 20001

202-434-4291

[langhorn@khlaw.com](mailto:langhorn@khlaw.com)

[www.khlaw.com](http://www.khlaw.com)

Washington, D.C. • Brussels • San Francisco • Shanghai