Objective: provide participants with enough knowledge of US FDA regulations for plastic food packaging to make their own compliance determinations

I. Background
II. Customary clearance determinations
III. Special clearance determinations
You also need to know

- US FDA system: not Global
- Good Manufacturing Practice: added obligation
- Ultimate Enforcer: Consumer

While this is a best effort to describe regulatory requirements for plastic food packaging, public concern about food safety raise expectations above minimal compliance.
I. Background

US law controlling food packaging has a minimal *statutory* foundation but a comprehensive *regulatory* structure

- **Regulations** - 21 CFR 170-199
  - Customary
  - Special
I. Background

US law controlling food packaging has a minimal *statutory* foundation but a comprehensive *regulatory* structure.

- **Regulations** - 21 CFR
  - Customary
  - Special

The US regulates food packaging material only if there is a reasonable expectation that, when used as intended, a part of it would become a component of the food [an “additive”] (with exceptions).
The law prohibits the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is *adulterated* or *misbranded*

- Food additives must have “premarket clearance” or food used with it is “unsafe and adulterated”
  - *Customary* premarket clearance
  - *Special* premarket clearance
Food Packaging Compliance: FFD&CA

- Can packaging component(s) enter the food?

- YES: Is/are component(s) cleared by US FDA?

- YES: Packaging material complies
Food Packaging Compliance: no regs!

Additive?

- Can packaging component(s) enter the food?

USE!

- No: No FDA clearance required!
Food Packaging: Non-compliance

Additive?

- Can packaging component(s) enter the food?

Approved?

- YES: Is/are component(s) cleared by US FDA?

STOP

- No: Packaging material fails to comply
II. Customary Clearance
21 CFR Part:
175 - Adhesives & Coatings
176 - Paper & Paperboard
177 - Polymers
178 - Adjuvants, Production Aids, Sanitizers

III. Special Clearance
- Generally Recognized as Safe
- Prior sanctioned
- Threshold of Regulation
- Food Contact Notification
These regulations list the customary “clearances” and detail the procedures for determining special “clearances” for food “additives” in general.

§170.6 “Over the years the FDA has given informal written opinions to inquiries as to the safety of articles intended for use as components of, or in contact with, food. Those written by the FDA after the Food Additives Amendments of 1958 remain in force.
Separated by Common Language 1

Additives
- Direct Additives
- Secondary Direct Additives
- Indirect Additives
More Language Barriers

**“ARTICLES”**
- jar
- can
- bottle
- bag

**“MATERIALS”**
- PP
- Al
- PET
- OPP

**“21 CFR”**
- 177.1590
- 177.1520
- 175!
Supply Chain Interdependence is critical
The regulation holds that *physical* blends ("mixtures") of substances are cleared if the individual substances have clearance.

- *Chemical* reaction by-products of sterilization or in-package food processing may or may not change the status of otherwise cleared substances
- *Chemical* reaction products of cleared substances are not assumed to have clearance
II. Customary Premarket Clearance

The customary clearance listings in 21 CFR 175-178 come with three simple underlying principles...

1. The *composition* of cleared materials must match that approved by FDA for the material.
2. The *quality* of cleared materials must meet FDA specifications for the material.
3. The cleared material must be *suitable* for its intended “use conditions” and “food types” as defined by US FDA.
Supply Chain communication is critical
<table>
<thead>
<tr>
<th>Part</th>
<th>Section</th>
<th>Material</th>
<th>Composition (e.g.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>175</td>
<td>.125</td>
<td>Pressure sensitive adhesive</td>
<td>Butylated reaction product of p-cresol and dicyclopentadiene produced by reacting p-cresol and dicyclopentadiene in an approximate mole ratio of 1.5 - 1.0, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 %, for use at levels not to exceed 1.0 % by weight of the adhesive formulation.</td>
</tr>
<tr>
<td>177</td>
<td>.1580</td>
<td>Polycarbonate</td>
<td>Monochlorobenzene</td>
</tr>
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<td>178</td>
<td>0178</td>
<td>Plasticizers</td>
<td>Diisononyl phthalate</td>
</tr>
<tr>
<td>Part</td>
<td>Material</td>
<td>Composition (e.g.)</td>
<td>Limitation</td>
</tr>
<tr>
<td>------</td>
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<td>Polycarbonate</td>
<td>Monoclorobenzene</td>
<td>Not to exceed 500 parts per million as residual solvent in finished resin.</td>
</tr>
<tr>
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<td>Plasticizers</td>
<td>Diisononyl phthalate</td>
<td>Not exceeding 43 pct by weight of permitted vinyl chloride homo-and/or copolymers used in contact with food only of the types identified in Sec. 176.170(c) of this chapter, table 1, under Categories I, II, IV-B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.</td>
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<tr>
<td></td>
<td>adhesive</td>
<td>Relative to adhesive mixture</td>
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<td>Relative to other section</td>
</tr>
</tbody>
</table>
21 CFR 176(c): “Table 1--Types of Raw and Processed Foods”

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).

II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.

III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.

IV. Dairy products and modifications:
   A. Water-in-oil emulsions, high- or low-fat.
   B. Oil-in-water emulsions, high- or low-fat.

V. Low-moisture fats and oil.

VI. Beverages:
   A. Containing up to 8 percent of alcohol.
   B. Nonalcoholic.
   C. Containing more than 8 percent alcohol.

VII. Bakery products other than those included under Types VIII or IX of this table:
   A. Moist bakery products with surface containing free fat or oil.
   B. Moist bakery products with surface containing no free fat or oil.

VIII. Dry solids with the surface containing no free fat or oil (no end test required).

IX. Dry solids with the surface containing free fat or oil.
21 CFR 176(c): “Table 2—Conditions of Use”

A. High temperature heat-sterilized (e.g., over 212 °F).
B. Boiling water sterilized
C. Hot filled or pasteurized above 150 °F.
D. Hot filled or pasteurized below 150 °F.
E. Room temperature filled and stored (no thermal treatment in the container)
F. Refrigerated storage (no thermal treatment in the container).
G. Frozen storage (no thermal treatment in the container).
H. Ready-prepared foods intended to be reheated in container at time of use:
   1. Aqueous or oil-in-water emulsion of high- or low fat.
   2. Aqueous, high- or low free oil or fat.
“New” Use Conditions

Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations

(applicable only to certain special clearance determinations)

J. Irradiation (ionizing radiation).
K. Cooking at temperatures exceeding 121 °C (250 °F).
Food Types & Use Conditions

Food Types-Chemistry
Interactions with the food’s chemistry that attract /release components of the packaging material into the food.

- Aqueous
- Oily
- Alcoholic

Use Conditions-Temperature
Temperature is the primary determinant of a given chemical reaction’s rate

- Refrigerated
- Frozen
- Pasteurized <150°F
- Pasteurized >150°F
- Boiling Water
- High Temperature Sterilized

Reheat in Container
**Oven Ease™ Bags**

- Re-heat fully cooked products such as hams and smoked turkeys
- Suitable cooking temps: up to 375°F (190° Celsius) for 4 hours

**Structure Materials**

- NYLON 6 adhesive resin
- POLYPROPYLENE
<table>
<thead>
<tr>
<th>Polymer</th>
<th>Section</th>
<th>Composition</th>
<th>Limitations*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nylon-6</td>
<td>177.1500</td>
<td>polymerization of epsilon caprolactam (Density: 1.15±0.15; $T_M$: 392-446°F)</td>
<td>Max wt% dissolved in: water, 1.0; 95% EtOH-2.0; EtAc-1.0; Benzene-1.0</td>
</tr>
<tr>
<td>Adhesive tie</td>
<td>175.1390</td>
<td>Maleic anhydride adduct of polypropylene complying with §175.300 of this chapter</td>
<td>Separated from the food contact layer by a functional barrier</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>177.1520</td>
<td>Catalytic polymerization of propylene; (Density: .880-.913; $T_M$: 160-180°C)</td>
<td>Max wt% dissolved in: n-hexane @ reflux, 6.4; Xylene @ 80°C 9.8</td>
</tr>
</tbody>
</table>

*None of these are specific to Food Type or Condition of USE

If “limitations” met, article is cleared for Food V with Use A
Functional Barrier

- Aluminum foil.
- FDA “may consider other layers to serve as functional barriers.” 177.1390 (a)
- No formal definition for functional barrier exists in the FFD&CA or in FDA regulations.*

* MAPP 5015.5 “Type III DMFs for Packaging Materials”
Functional Barrier

- Aluminum foil.
- FDA “may consider other barriers.” 177.1390 (a)
- No formal definition for functional barrier exists in the FFD&CA or in FDA regulations.*

* MAPP 5015.5 “Type III DMFs for Packaging Materials”

A “functional barrier” in food contact packaging material is a layer that prevents the migration of materials’ components from the outer layers to the food.
Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

- Substances generally recognized as safe in or on food.
- Substances generally recognized as safe for their intended use in food packaging.
- Substances used in accordance with a prior sanction or approval.
- Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and Sec. 179.45 [irradiation] of this chapter.
- Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.
In addition to the customary compliance based on composition & specification clearances of 21 CFR 175-178, clearance by one of the following procedures is valid:

- Generally Recognized as Safe (GRAS)
- Prior Sanctioned
- Threshold of Regulation (TOR)
- Food Contact Notification (FCN)
# Special Clearance Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CFR Listing</th>
<th>Official List?</th>
<th>Ad Hoc clearance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generally Recognized as safe</td>
<td>Some</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Prior sanctioned</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Threshold of Regulation</td>
<td>No</td>
<td>No</td>
<td>Yes*</td>
</tr>
<tr>
<td>Food Contact Notification</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
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</table>

*Effectively “GRAS”*
It is impracticable to list all substances that are generally recognized as safe for their intended use. .. such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use.

A substance that becomes a component of food as a result of its use in the ... packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

When the status of a substance has been reevaluated, it will be deleted from this part [182], and will be issued as a new regulation under the appropriate part, e.g., ``affirmed as GRAS'' under part 184 [Direct] or 186 [Indirect] of this chapter...
Substances reviewed by the FDA and determined to be GRAS for the purposes and conditions prescribed, must be of purity suitable for their intended use.

Certain ingredients in this part may also be used in food-contact surfaces in accordance with parts 174, 175, 176, 177, 178 or §179.45 of this chapter.

Ingredients affirmed as GRAS for direct use in part 184 of this chapter are also GRAS as indirect human food ingredients in accordance with that chapter.
A prior sanction shall exist only for specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the FDA or the USDA prior to September 6, 1958.

The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but not from the other adulteration or the misbranding provisions of the Act.

All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingredient, or revocation to prohibit use of the ingredient.
A substance in a food-contact article that migrates, or may be expected to migrate, into food will be exempted by FDA from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

- The substance has *not been shown to be a carcinogen* in humans or animals, and there is no reason, based on the chemical structure of the substance, to suspect that it is.

- The substance presents *no other health or safety concerns* because:
  - use in question will result in *dietary concentrations at or below 0.5 parts per billion*, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (a daily diet of 1,500 grams of solid food and 1,500 grams of liquid food)
  - The substance is currently regulated for direct addition into food, and the dietary exposure to the substance resulting from the proposed use is at or below 1 percent of the acceptable daily intake as determined by safety data in the FDA’s files or other appropriate sources
“Recent” legislative authorization- Food and Drug Administration Modernization Act of 1997 (FDAMA)

Effectively replaces the administration of additions to 21 CFR Parts 175-178 with significant changes

- FDA must accept/deny a “complete” application within 120 days of filing
- An Internet –based ”Inventory of Effective Food Contact Substance (FCS) Notifications” replaces any amendments to 21 CFR Parts 175-178: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm
- The FCN gives “food additive clearance” only to the specific product documented in the application (effectively to the applicant rather than the substance)
- 1120 listed as of 31 Dec 2011.
FCN Application

<table>
<thead>
<tr>
<th>Compressive Summary</th>
<th>Estimation of Intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Identity</td>
<td>Toxicity Information</td>
</tr>
<tr>
<td>Intended Conditions of Use</td>
<td>Environmental Information</td>
</tr>
<tr>
<td>Intended Technical Effect</td>
<td></td>
</tr>
</tbody>
</table>

1. FDA Form No. 3480
(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076880.pdf)

2. FDA Guidance:
   Chemistry
   http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm124917.htm
   Toxicology
   http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm

2/8/2012
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Background

Materials used in food contact packaging must have premarket clearance by the USFDA if substances in them could migrate into the food.

Customary Premarket Clearance

Cleared adhesives, polymers and additives are defined by composition and quality specifications in suitable applications by 21 CFR 175-178.

Special Premarket Clearance

Additional procedures for determining the clearance of a material (or its status as unregulated) may be proper, including some involving self determinations.
Thank you for your attention!

Questions?

Now...or Tom Dunn (tdunn@flexpacknology.com)