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Plastics in Plain Language – A Roadmap to FDA Regulation

December 10, 2019

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Plastics in Plain Language

About the Presenter

- 10 years experience as an attorney focusing on global regulation of food packaging, food ingredients, and tobacco/e-vapor products
- Background in Industrial Engineering
- Former supply chain engineer for medical device manufacturing company
- Pennsylvania native; lived in Pittsburgh from 2002-2007

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Today's Presentation

- Regulation of food contact materials is complex, but –
- Concepts shouldn't have to be difficult to explain
- Brief introduction to FDA regulation of food-contact materials…
- …in ways that you can understand and communicate to your team

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Why Plain Language?

- **Advice** is only helpful if you can **understand it**
- Things that **aren't understood** are often **ignored**
- Information that is **ignored** can result in **increased costs** and **exposure** to the business

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In the beginning (prior to the late 1800's)…

- Everything was *local* – no way to move products long distances
- Food was manufactured, held and transported under dirty conditions
- Drugs contained mysterious, dangerous, or addictive ingredients (or none at all!)
- Federal oversight was practically non-existent

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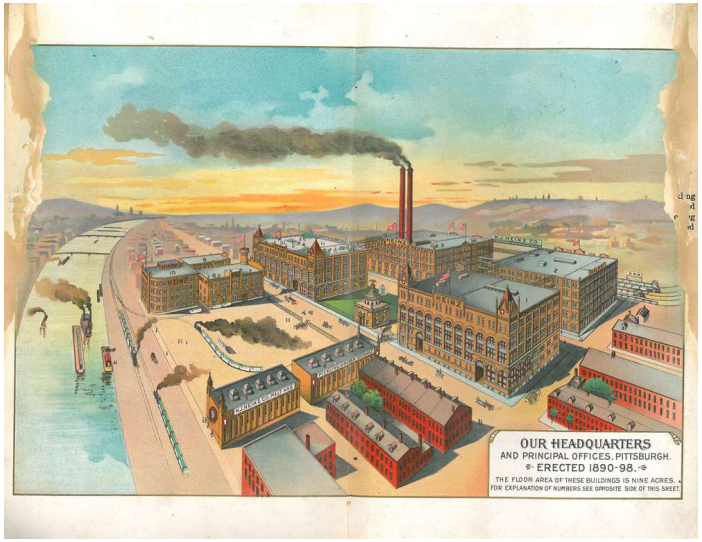
Then: "a Book, a Bulb, and a Railroad"

- Three major developments changed food regulatory history:
  - The first transcontinental railroad (1869)
  - Food manufacturers began to use electricity to modernize and mass produce (1869) (H.J. Heinz)
  - Upton Sinclair wrote *The Jungle* (1906)



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Public Outcry

"I aimed at the public's heart, and by accident I hit it in the stomach."
- Upton Sinclair

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Congress Catches Up (Eventually)

- **Pure Food Act** (1906)
  - Federal government could now regulate food and drugs placed in "interstate commerce"
- **Federal Food, Drug, and Cosmetic Act** (1938)
  - Significantly expanded scope of FDA authority to include medical devices and cosmetics
  - Foundation for today's modern food packaging regulatory scheme
- **Food Additive Amendment of 1958**
  - Included "food additives" in the purview of FDA's required safety reviews
  - Established an exemption from the definition of "food additive" (GRAS)
  - Implemented the Delaney Clause (carcinogenic constituents)

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FDA Regulation of Food Packaging

- Laws and regulations based primarily on **Food, Drug, and Cosmetic Act of 1938** and the definition of a **food additive** introduced in the **Food Additives Amendment of 1958.**
  - Food shall not be **adulterated** – unsafe or unfit for consumption (off-taste/odor)
  - Food shall not be **misbranded** – false or misleading label, container, ingredient

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FDA Regulation of Food Packaging

- What is a **food additive?**

So, not all food contact substances are food additives!

  - Any **substance**
  - The **intended use** of which
  - **Results**, or may **reasonably be expected to result**
  - In its **becoming a component** of or **otherwise affecting** the characteristics of **food**

(Unless it is the subject of an exemption or exception…)

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FDA Regulation of Food Packaging

- Three types of potential food additives:
  - **Direct** – substances added *directly* to food (ingredients)
  - **Secondary Direct** – substances used during *processing*, but removed before eating
  - **Indirect** – substances that come into contact with food during packaging, holding or processing, but are not:
    - Intended to be directly added to food
    - Intended to have a technical effect in or on food

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"The Toolkit"

- Everything that follows are simply different ways to establish a suitable FDA status for an indirect food additive:
  - Food Additive Regulation
  - No Migration Exemption
  - GRAS Exemption
  - Other Exemptions and Exceptions
  - Food Contact Notifications (FCN)

*Don't forget about suitable purity and good manufacturing practice

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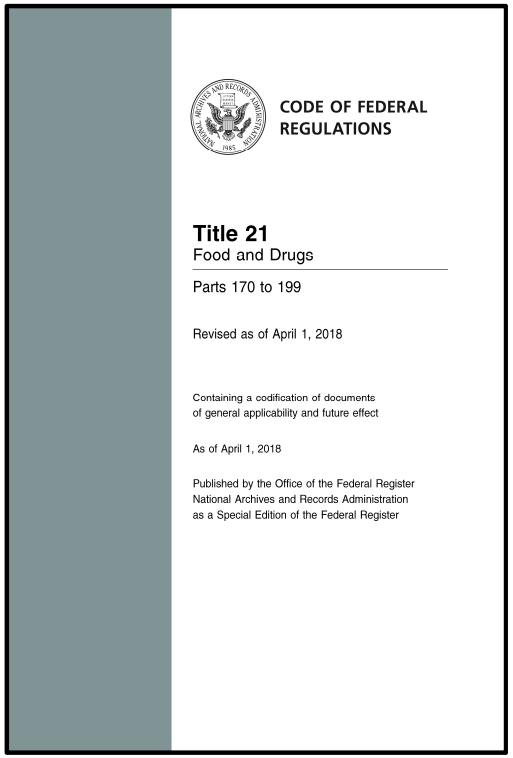
In Plain Language: The Food Additive Regulations

<u>Congress to FDA:</u> "You're in charge. Write the rules."
(Federal Food, Drug, and Cosmetic Act of 1938)

<u>FDA:</u> "Here are the rules."
(Food Additive Regulations)



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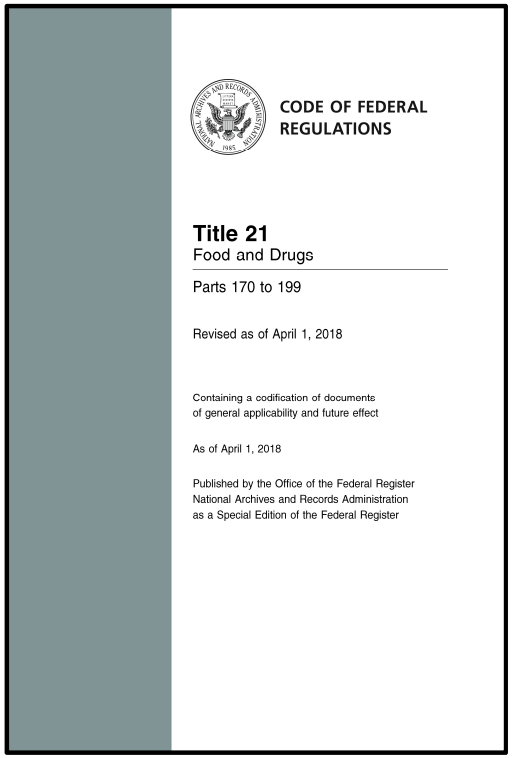
In Plain Language: The Food Additive Regulations

- Adhesives (Section 175.105)
- Coatings (Sections 175.300 and 175.320)
- Components of Paper and Paperboard (Sections 176.170/80)
- Polymers and Polymeric Substrates (Part 177)
- Processing Aids and Additives (Part 178)

Food Contact Substances that are used in accordance with the Food Additive Regulations are already the subject of premarket approval by FDA – no further action is needed.



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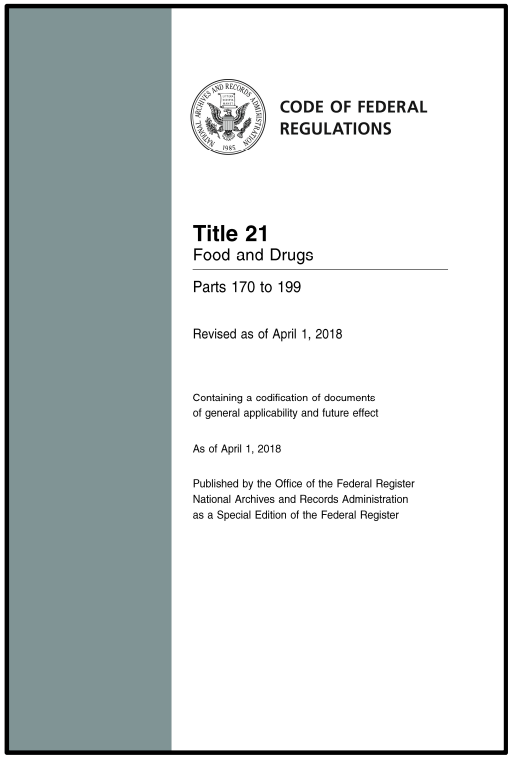
In Plain Language: The Food Additive Regulations

But…

- The regulations were originally written in the 1950s and 1960s
- They are now rarely updated and require a lengthy petition process
- Most recent developments include *de-listing* substances that are no longer used by industry (abandonment)

By necessity, FDA and industry had to adapt to rapid changes in product innovation and regulation outside of the traditional food additive regulation concept.



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In Plain Language: No Migration

Congress to FDA:
Substances that do not migrate from packaging to food in more than insignificant amounts are not food additives

(Monsanto v. Kennedy, 1979)

FDA Official to the Public:
Insignificant amounts should mean less than 50 parts per billion (ppb) unless the substance presents a special safety concern (heavy metals, carcinogens)

(Lessel Ramsey to the Society of Plastics Engineers, 1969*)

*Proposal that was never officially adopted by FDA, but upon which industry has come to rely.

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In Plain Language: No Migration

- Comes from the definition of a **food additive…**
  - Any **substance**
  - The **intended use** of which
  - **Results**, or may **reasonably be expected to result**
  - In its **becoming a component** of or **otherwise affecting** the characteristics of **food**

- If a substance is **not** reasonably expected to become a component of food,
- The substance is **not** a food additive, and therefore,
- The substance does **not** require premarket clearance.

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In Plain Language: No Migration

- What is "no" migration?
- Zero is a concept, not a number
- FDA and industry used to rely on "default values" (50 ppb), but the general availability of toxicity data now often precludes the need to rely on assumptions - science has evolved!

- **A company decides for itself whether "No Migration" applies – not FDA.**
  - Worst-case (100%) migration calculations
  - Analytical modeling (*e.g.*, diffusion analysis)
  - Migration testing using appropriate food-simulating solvents, times and temperatures

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In Plain Language: GRAS Exception

<u>Congress to FDA:</u>
"Certain substances that are 'generally recognized'
by scientific experts
as safe for use in food
are exempt from the definition of 'food additive,'
provided that appropriate scientific procedures are used to demonstrate safety
or there is a history of safe use in food demonstrates (prior to 1958)"

(Food Additives Amendment Act of 1958)

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In Plain Language: GRAS Exception

- Designed to reflect practical realities of 1958:
  - People have been eating certain foods since the beginning of time without any issue
  - FDA lacked the capacity (funding, personnel) to regulate every one of these substances

- Two types of "GRAS" evolved:
  - **Substances listed or affirmed as GRAS** for direct addition to food (21 C.F.R. Parts 182, 184 and 186)
  - **Industry self-affirmations** of GRAS status (public and private determinations)

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In Plain Language: GRAS Exception

- **Substances listed or affirmed as GRAS**
  - Food additive regulations contain two lists of substances used in food prior to 1958:
    - Substances "listed" as GRAS – original Part 182
    - Substances "affirmed" as GRAS – moved to Part 184
      (FDA evaluated substances listed in Part 182 'affirmed' these listings)
  - There is a third list, for indirect additives, in Part 186 (but cross-reference!)
  - These lists are <u>not</u> exhaustive!

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In Plain Language: GRAS Exception

- **Industry Self-Affirmations of GRAS Status**

Prior to 1958	After 1958
A substance that is *generally recognized as safe* – by experts qualified by scientific training to evaluate a substance's safety – based on:	
Common use in food; or	-
Scientific procedures	Scientific procedures (only!)

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In Plain Language: GRAS Exception

- **Scientific Procedures**
  - The same quality and quantity of information that you would need for a Food Additive Petition
  - Requires reliance primarily on "publicly available" information
  - Supported by unpublished studies, information, and evidence

- In practice, GRAS conclusions by industry are based on the amount of a substance that could potentially be present in the diet (for substances migrating from food packaging, often at part-per-billion or part-per-trillion levels – another presentation for another day!)

- Industry "self-GRAS" determinations or GRAS Notice (food ingredients) – "have a nice life" letters

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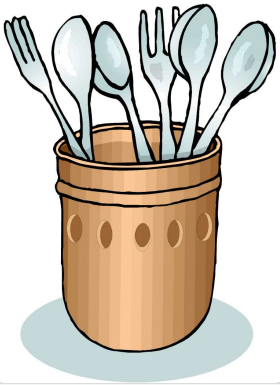
In Plain Language: Other Exemptions and Exceptions

- **Functional Barrier:** *If a substance can't migrate through a functional barrier, it is not a food additive*
- **Prior-Sanctioned Substances:** *Substances that FDA "sanctioned" through letters to industry issued prior to 1958*
- **Housewares Exemption:** *Substances used to prepare or serve food in the home are generally not subject to premarket approval requirements (but must still be safe!)*



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In Plain Language: Other Exemptions and Exceptions

- **Basic Resin Doctrine:** *Substances that are necessary to the manufacture of a polymer; are used at low levels; are generally expected to be removed or not available to migrate to food; and do not present a health or safety concern, do not require premarket approval.*

- **Threshold of Regulation Exemption (21 C.F.R. 170.39):** *FDA provides letters to industry exempting the use of substances from the need for premarket approval when the intended of a substance results in a dietary exposure of less than 0.5 ppb and does not raise special toxicity concerns.*

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In Plain Language: Food Contact Notification

<u>Industry to FDA:</u>
It's taking way too long to get new packaging products on the market.
We need a more efficient alternative to the process for food ingredients.
(A really long time)

<u>FDA to Industry:</u>
The Food Contact Notification Program
(January 2000)

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Food Contact Notification

- Effectively replaces the more cumbersome process of filing a Food Additive Petition
- Company submits information to FDA demonstrating safety of substance when used as intended:
  - Chemical identity
  - Intended use
  - Manufacturing information
  - Safety assessment (exposure assessment, comprehensive toxicology profile)
  - Environmental assessment (where required)
- FDA required to review and respond within 120 days (subject to extensions)
- FCNs are proprietary to the manufacturer and its customers

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Brief Recap

- Innovation drove the need for regulation
- Congress (eventually) gave FDA authority they needed to pass regulations
- FDA regulations represented a first attempt in 1958, but…
- Innovation drove the need for alternatives to formal regulation
- FDA, Congress and the courts responded with new and innovative approaches
    - Exemptions, exceptions, and streamlined notification processes

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Thank You!

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