
FDA and International Regulation of Food-Contact Substances

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Presentation Topics

- Description of FDA's Food-Contact Notification System
- Alternatives to Food-Contact Notifications for Establishing FDA Compliance
- Overview of Systems Used by Other Countries

Food-Contact Notification

- FDA stopped treating food-contact substances like direct food additives
- Much faster clearance
- Full protection of public safety

When Is the Substance Cleared?

- Old System
 - Packaging material was not “legal” until FDA published a regulation
- New System
 - Packaging material is automatically “legal” unless FDA objects within 120 days

How the FCN System Was Created

- Food and Drug Administration Modernization Act of 1997 (FDAMA)
- Effective January 18, 2000
- It took Congress a while to come up with the money

Key Benefit to Industry – Much Faster FDA Action

- Old System
 - Food additive petition process
 - 2-4 years
- New System
 - Food-contact notification process
 - 120 days

Notifications Are Proprietary

- Effective only for company that filed the notification and its customers
 - Artifact of original user fee concept
- Competitors must file their own notifications
 - Can obtain much of first filer's data
- Anyone can rely on a food additive regulation

Notifications Replace Petitions and Threshold of Regulation Requests

- Existing regulations and threshold of regulation determinations remain valid
 - Threshold of regulation procedure exists, but effectively superseded except in a few special cases
- Inventory of effective FCNs available at:
 - <http://www.cfsan.fda.gov/~dms/opa-fcn.html>

Food-Contact Notification Does Not Eliminate Exemptions

9

- Any food-contact substance may be the subject of a notification
- Not all food-contact substances require a notification

Definition of Food-Contact Substance

- Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food
- If such use is not intended to have a technical effect in food

Definition of Food Additive

- Any substance the intended use of which results in or may reasonably be expected to result ... in its becoming a component of food ... if such substance is not generally recognized as safe ... except such term does not include –
 - (4) Any substance used in accordance with a sanction of approval granted prior to [1958]

FDA Regulation of Food-Contact Substances

- If a food additive, premarket clearance required
- If not a food additive, premarket clearance not required
- Food additive status – self-determination

Exemptions from FDA Clearance

- No migration
- Functional barrier
- GRAS
- Prior sanction
- Basic resin doctrine
- Housewares

No Migration

- A substance not reasonably expected to become a component of food is not a food additive
- *Monsanto v. Kennedy*: FDA must find that a substance migrates into food in more than insignificant amounts to consider it to be a food additive

No Migration II

- No migration
 - What does “no” mean?
 - 50 ppb, sometimes 10 ppb or less
- 100% migration, modeling, or testing
- Self-determination

Functional Barrier

- Substances separated from food by a barrier that prevents their migration to food are not considered to be food additives
 - Adhesives
 - Multi-layer, laminated structures
 - Labels, printing, coating on exterior

All Barriers Are Not Functional

- The fact that a substance is on the non food-contact side does not automatically make it exempt
- Often requires calculation or migration testing

Generally Recognized as Safe (GRAS)

- Pre-1958 use
- Common knowledge of safety in the scientific community
 - Key toxicology data must be published

GRAS II

- Some in regulations (Parts 182,184,186), some not
- Self-determination
 - Low dietary exposure
- Fluid concept
 - Can shift with scientific knowledge
- GRAS notification procedure

GRAS III

Substance that is GRAS for use in food is GRAS for use in food packaging

However

FDA clearance of a substance in a direct food additive regulation (in 21 CFR Part 172) or by a food-contact notification does not sanction its use in food packaging. Such clearances may support a self-determined GRAS position, provided that exposure from the packaging use is significantly lower than exposure from the direct use

Prior Sanction

- Pre-1958 approval by FDA or USDA
 - Private letters
- Lehman List
- Part 181

Basic Resin Doctrine

- Food additive regulations establish clearance for substances, not manufacturing processes
 - Indirect food additive regulations typically do not include substances added to the reactor as processing aids in manufacturing polymers

Basic Resin Doctrine II

- Applies to food-contact notifications
- FDA does not require identification of basic resin substances on inventory of effective notifications
- FDA does review basic resin substances for safety in reviewing notifications

Basic Resin III

- Under regulations or notifications, basic resin substances can be changed without FDA's permission, as long as the manufacturer confirms the safety of the change
 - Documentation of the safety determination is highly recommended

Housewares Exemption

- Legislative history of the 1958 Food Additives Amendment
 - Congress did not intend that housewares (or their components) would be subject to the requirement for FDA premarket clearance
- Housewares are articles used by consumers or food-service establishments to prepare, hold, or serve food.
 - Examples: Utensils, plates, food storage containers, clamshells, paper or plastic food wraps
- FDA premarket clearance is not required for housewares or their components
 - Manufacturer must ensure safety

International Systems

- Positive List – EU, Canada (CFIA), Mercosur, South Korea, China (under construction)
- Japan – Unique combination of government regulation and industry standards
- FDA/EU or general safety standard – Australia/New Zealand, Non-Mercosur South America, Hong Kong, Singapore, Taiwan, Thailand

Thank You

