A Beginners Guide to FDA Legislation of Food Contact Materials

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Introducing Dr Alistair Irvine

Alistair manages the Food Packaging Safety Section within Smithers Pira. This involves advising clients on the safety legislation which applies to food packaging in a wide range of different countries throughout the world and coordinating work programmes to ensure that clients' products meet these requirements.

His expertise spans all the EU countries, USA, Japan, Australia, New Zealand, Canada, Israel, Russia and all the South American countries.
Today’s Webinar will focus on:

- How the FDA regulates Food Contact Materials.
- The Code of Federal Regulations or the FDA Regulations (CFR21 parts 170-199).
- The role of Food Contact Notifications.
- Exemptions from FDA Regulation.
- Q&A
• If you have come to this session looking for a deep dive into the approval processes for food contact materials in the USA, this may not be the presentation for you. We will present on that subject in a future webinar though.

• This webinar will offer a general overview of how food contact materials are regulated in the USA.

• Please bear in mind that the guidance in this talk does not represent legal advice.

• Also, bear in mind that the FDA regulations are quite complex and can take very careful reading.
A Short History of US Food Law

- 1906 Food And Drug Act (No requirements on food contact materials)
- 1938 The Federal Food, Drug, and Cosmetic Act (Still no requirement relating to food contact materials, but a lot of the mechanisms which support the legislation were set up).
- 1957 Amendment to the FFDCA brought food contact materials under the scope of the regulation. This came into effect in 1958.
How does the FDA regulate FCMs?

• Section 201(s) of the act, a food additive is defined as “any substance the intended use of which results in or may reasonably be expected to result ....in its becoming a component of food”

• Substances passing into food from packaging are therefore regarded as ‘indirect food additives’
There are essentially 3 routes to FDA compliance:

- For many established food contact materials, there will be an existing specific FDA regulation dealing with that material. 21CFR Parts 170-199.
- For new food contact substances, you will probably need to seek authorisation from FDA. FCNs and Threshold of Regulation.
- If you can argue that the substance is not covered by the scope of FFDCA, FDA approval is not required.
These are mostly what people refer to as the ‘FDA Regulations’.

Cover almost all classes of food packaging
- Plastics; polyolefins, polyesters, polystyrene, polyamides and many many more
- Paper and cardboard
- Polymeric coatings
- Additives
- Adhesives

The majority of everyday food contact materials can usually be made with Food Contact Substances which are covered by one of these regulations.

They are therefore a primary source of information when considering whether a food contact material can be placed on the US market.
• Relevant Sections can be found in 21 CFR Parts 170 to 199.
• Available as hard copy, but [almost] no-one bothers because….
• Also available for free at web site;
• Regulations updated usually on April 1, so please be careful with link (which links through to the 2016 regulations - still current at time of writing though).
When do you use 21CFR 170-199?

- Whenever you are working with long established materials?
  - In the case of polymer producers, this will be when you are placing conventional packaging polymers (or papers, additives, coating etc.) on the market.
  - In the case of packaging manufacturers, where all of your raw materials are certified against existing FDA regulations.
Where did the regulations come from?

- FDA over a long period of time invited producers of food contact materials to register the materials under a Food Additive Petition (FAP).
- Applicants submitted dossiers based on FDA guidance at the time. This would involve a measurement of migration, and calculation of dietary exposure which FDA would then compare with toxicological information to reach a determination of safety.
- Successful applications became transferred into a regulation.
- The FDA guidance changes periodically and leaves some room for differing approaches.
- As a result, the regulations that come out of this process vary greatly in form.
- The process is still open, but is not used so much now that the Food Contact Notification System is open.
How is 21CFR laid out?

Part

170-173 Mostly concerned with Direct Food Additives
174 Indirect food additives: General
175 Indirect food additives: Adhesives and components of coatings
176 Indirect food additives: Paper and paperboard components
177 **Indirect food additives: Polymers**
178 Indirect food additives: Adjuvants, production aids, and sanitizers
181 Prior-sanctioned food ingredients
182-186 Substances generally recognized as safe
189 Substances prohibited from use in human food
190 Dietary supplements
Individual Regulations

Section

177.1500 Nylon resins.

177.1520 Olefin polymers.
177.1550 Perfluorocarbon resins.
177.1555 Polyarylate resins.
177.1556 Polyaryletherketone resins.
177.1560 Polyarylsulfone resins.
177.1570 Poly-1-butene resins and butene/ethylene copolymers.
177.1580 Polycarbonate resins.
177.1585 Polyestercarbonate resins.
177.1590 Polyester elastomers.
177.1595 Polyetherimide resin.
177.1600 Polyethylene resins, carboxyl modified.
177.1610 Polyethylene, chlorinated.
177.1615 Polyethylene, fluorinated.
177.1620 Polyethylene, oxidized.
177.1630 Polyethylene phthalate polymers.
§177.1520 (Polyolefins)

• Contains definitions of individual types of polyolefins – if your polymer doesn’t meet any of these definitions, it isn’t covered by this regulation.
• Lists permitted additives, where these are not covered by general lists
• Contains specifications for polymers subdivided by polymer type and application. Specifications include density, melting point and hexane and xylene extractable material as a percentage.
• Test methods also specified.
• End use restrictions on applications in which resins used (i.e. restrictions on food types and temperatures).
• As long as the resin complies, there is no need for finished article to be tested.
What isn’t in the Regulations?

- Anything which is listed generally (elsewhere in the regulations) as a Direct or Indirect Food Additive.
- Anything considered as exempt from regulation.
- FDA regulations generally (but not exclusively) tend to focus on the final chemical composition and not the monomers.
A Grade of HDPE contains 500 ppm of Octadecyl-3,5-di-tert-butyl-4-hydroxyhydrocinnamate (Irganox 1076).

This is not listed in the short list of approved substances specifically mentioned under 21CFR §177.1520.

It is listed in Regulation §178.2010 (antioxidants)

In this regulation, it is specifically approved for use ‘At levels not exceeding 0.25 wt% of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4.’

It is therefore approved for use in HDPE by cross referencing.
Tips for Working with 21CFR Parts 170-199

• Read the regulations you are working with very very carefully.
• Take particular care when you are trying to support the use of a substance in a plastic (or any other application) based on a listing in a separate regulation. Make sure the approval for the substance will cover what you want to do with it.
• Watch out for end use restrictions. Not all materials are suitable for use with all types of food under all temperatures.
• If you are going to work with the FDA regulations a lot, try to get to grips with Tables 1 and 2 of Regulation 176.170 on paper.
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.
### Table 2—Test Procedures with Time Temperature Conditions for Determining Amount of Extractives From the Food-Contact Surface of Uncoated or Coated Paper and Paperboard, Using Solvents Simulating Types of Foods and Beverages—Continued

<table>
<thead>
<tr>
<th>Condition of use</th>
<th>Types of food (see table 1)</th>
<th>Food-simulating solvents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Water</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time and temperature</td>
</tr>
<tr>
<td>C. Hot filled or pasteurized above 150 °F ....</td>
<td>II, IV-B, VII-B ....</td>
<td>Fill boiling, cool to 100 °F.</td>
</tr>
<tr>
<td></td>
<td>III, IV-A, VII-A ....</td>
<td>do</td>
</tr>
<tr>
<td>D. Hot filled or pasteurized below 150 °F ....</td>
<td>V, IX</td>
<td>do</td>
</tr>
<tr>
<td>E. Room temperature filled and stored (no thermal treatment in the container)</td>
<td>VII-B</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>III, IV-A, VII-A ....</td>
<td>do</td>
</tr>
<tr>
<td>F. Refrigerated storage (no thermal treatment in the container)</td>
<td>V, IX</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>VI-A</td>
<td>120 °F, 24 hr</td>
</tr>
<tr>
<td></td>
<td>VI-C</td>
<td>70 °F, 48 hr</td>
</tr>
<tr>
<td></td>
<td>III, IV-A, VII-A ....</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>I, II, IV-B, VI-B, VII-B</td>
<td>70 °F, 48 hr</td>
</tr>
</tbody>
</table>
Things to watch out for in 21CFR 170-199

• Very often approvals have restrictions placed upon them.
• For example, you could find something the following wording on a food contact statement for an FDA compliant material.
  – Reynholm Industries Polymer X may be used as a barrier layer in multilayered plastics films and can be used to package all types of foods under Conditions B through H of 21CFR 176.170 (c) Table 2.
• Where restrictions like this are present in a regulation they need to be respected.
• It creates a need for information transfer from the raw material supplier to the user.
Why did the FAP System fall out of favour?

- Where a food contact material is cleared under the Food Additive Petition System, the resulting Regulation in 21CFR is Generic, which means that any producer of similar materials can use that regulation to show safety for their products.
- This is obviously good for end users, but if you have spent a lot of money to register a new polymer, you would probably prefer a proprietary approval.
- The FDA were always understaffed in the section which evaluates FAPs, so they took a long time to review dossiers.
- A quicker and proprietary system was therefore devised by FDA.
Route 2: Food Contact Notification Program

  - Formal Process and Clearly defined package of information required.
  - 120 day clock for FDA to raise objections.
  - If they do not, the packaging material is automatically legal.
  - Program periodically comes under budgetary review.
Information Required by FDA to support an FCN

• Migration Study
  – A measure of how much of the substance migrates into foods using the FDA’s standard protocols.

• Estimate of Dietary Exposure
  – Using the FDA’s standard dietary exposure model to estimate amount of the substance in the daily diet. The same model that is used for an FAP.

• Toxicological Review
  – Depending on the level of dietary exposure, the FDA will ask for differing levels of toxicological information.
  – For the highest levels of exposure, they will still ask for an FAP.

• Environmental Impact Assessment
FDA Process for FCNs

• FDA offer a Pre-Notification Consultation meeting (either by phone or in person) to help work with you to iron out any minor blemishes before the dossier is submitted.
• FDA have a rapid (< 120 day) turnaround on the review process. They are able to do this because much of the burden or assessment has been passed back to the petitioner.
• Assuming the FCN is granted, it will be published in the FDA’s inventory
  – www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCSS/Notifications/default.htm
Who would apply for an FCN?

• Typically, the producer of the food contact substance would apply for it to be registered.
• What would trigger this would be;
  – When they wish to place a new food contact substance on the market or
  – When they wish to use a substance which is already approved under an FCN under new conditions which go beyond the scope of its existing approval (e.g. using an existing antioxidant in a different plastic or at higher levels than previously approved).
• Users of food contact substances (i.e. packaging manufacturers) would not normally apply for FCNs as it would be unlikely they could ever be in a position to recoup the costs.
• Users would therefore mostly rely on preapproved substances.
What does this mean for packaging manufacturers?

• Clearly the first task is to gather food contact statements for FCN substances.
• These might also contain restrictions;
  – *Reynholm Industries Product Y will comply with USA FDA regulations under FCN 1999. This notification allows for use of this product in contact with all types of food Under Conditions of use C-H as described in Table 2 of 21CFR Section 176.170.*
• Where a substance like this is used, these restrictions would need to be respected and communicated downstream to users.
• Also, because an FCN approval is proprietary, to rely on this FCN, you would need to ensure that the material is produced by Reynholm Industries.
Other routes for formal FDA Review

- Threshold of Regulation Mechanism for very low exposure substances (<0.5 ppb in the diet).
- Approval of plastics recycling processes.
- Formal review of Generally Recognised as Safe status.
Route 3: Exemptions from FDA regulation

• There are a number of widely used packaging materials which are exempt from the FDA regulations.
• Just because your substance isn’t listed, it doesn’t mean it can not be used, but there are limits!
- Prior Sanction
- Substances Generally Recognised as Safe
- No Migration Exemption
- Basic Resin Doctrine
- No Migration Exemption
- Mixture Doctrine
- Functional Barriers and Threshold of Regulation
- Housewares Exemption
Prior Sanction

- Food packaging first brought under Food and Drugs Act in an amendment of 1958
- Before this, the FDA had previously approved many inquiries from manufacturers regarding suitability of food substances or packaging.
  - *De Facto* recognition of these prior sanctions granted in 1958 and continues in force.
  - Prior sanction status is merely a statement of fact depending on the existence of an approval letter prior to 1958.
  - PVC is the most notable example of a Prior Sanction.
Substances Generally Recognised as Safe; GRAS

- List is given in 21 CFR Parts 182 (General Provisions), 184 (Direct Food Additives) and 186 (Indirect Food Additives).
- Direct Food Additives covered by GRAS are also OK as plastics additives (e.g. zinc oxide and zinc stearate).
- Options exist for self determination of GRAS status of a substance.
Self determination of GRAS Status

• Laid out in 21 CFR §170.30
• Requires Common Knowledge of substance throughout scientific community.
• For substances not widely used in food before 1958, requires same quantity and quality of information as an FCN
• Therefore not widely used for new substances.
• Needs and expert and/or lawyer to advise on this.
• Self-GRAS is currently a contentious issue in the area of direct food additives. No problems have been raised in respect of packaging ingredients, but care is required.
No Migration Exemption

- Ties back to the Food and Drugs Act
- If a substance is not reasonably expected to become a component of food, it is not considered an additive and therefore will not be covered by the act.
- Provides the most used route to self-determination that a food additive is not subject to FDA review.
The Ramsey Proposal

• Where do you stop worrying about migration?
• No migration is interpreted as less than 50 ppb, except for high exposure applications such as milk and Carbonated Soft Drink bottles and for biologically active molecules where a 10 ppb limit applies.
• Must not be known to pose special toxicological concerns (e.g. heavy metals or carcinogens), and must not be known not to pose toxic reactions at levels of 40 ppb or lower in the diet of man or animals.
• Confirmed by a Legal Case; Monsanto vs Kennedy 1979
How do you demonstrate “No Migration”

- Modelling or testing permitted.
- Assumptions of 100% migration calculations.
- Self determination (although you may prefer someone with expertise and public liability insurance to carry out the calculation).
- No need to notify FDA.
Summary

We’ve seen how there are three distinct routes to demonstrate compliance for the FDA food contact regulations:

- For many well-established food contact materials, these will be covered by the FDA Code of Federal Regulations 21CFR 170-199.
  - When relying on these, please read them well and make sure you understand the regulations you are using and the need for onwards dissemination of information.
- For New food contact materials, the primary route for approval is now the FCN system.
  - Again look out for end use restrictions and remember that the FCN only applies to the company who own the FCN.
- It is also possible to claim exemption from FDA regulation, but you should do so only with care.
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