The Basics of the U.S. FDA's Regulation of Materials Used in Food Packaging Applications

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Agenda

- FDA’s regulation of food contact materials
- FDA's regulation of printing inks used in food contact materials

FDA's Regulation of Food Contact Materials

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How Are Food-Contact Materials Regulated in the United States?

- Food-contact materials are regulated in the U.S. as “food additives”
- Food additives are presumed to be unsafe unless a suitable FDA status has been established

1958 Food Additives Amendment

- This law led to the requirement that all “food additives” had to be pre-cleared by FDA before one could legally market the substance in the U.S.

- The law was passed because there was concern that things were being added to food, or becoming components of food, that were not safe and causing cancer

Food Additives

What is a “Food Additive”?

Any substance that is reasonably expected to become a component of food under the intended conditions of use, unless the substance is subject to an exemption.

Some exemptions include:

- The substance is prior-sanctioned
- The substance is generally recognized as safe (GRAS)

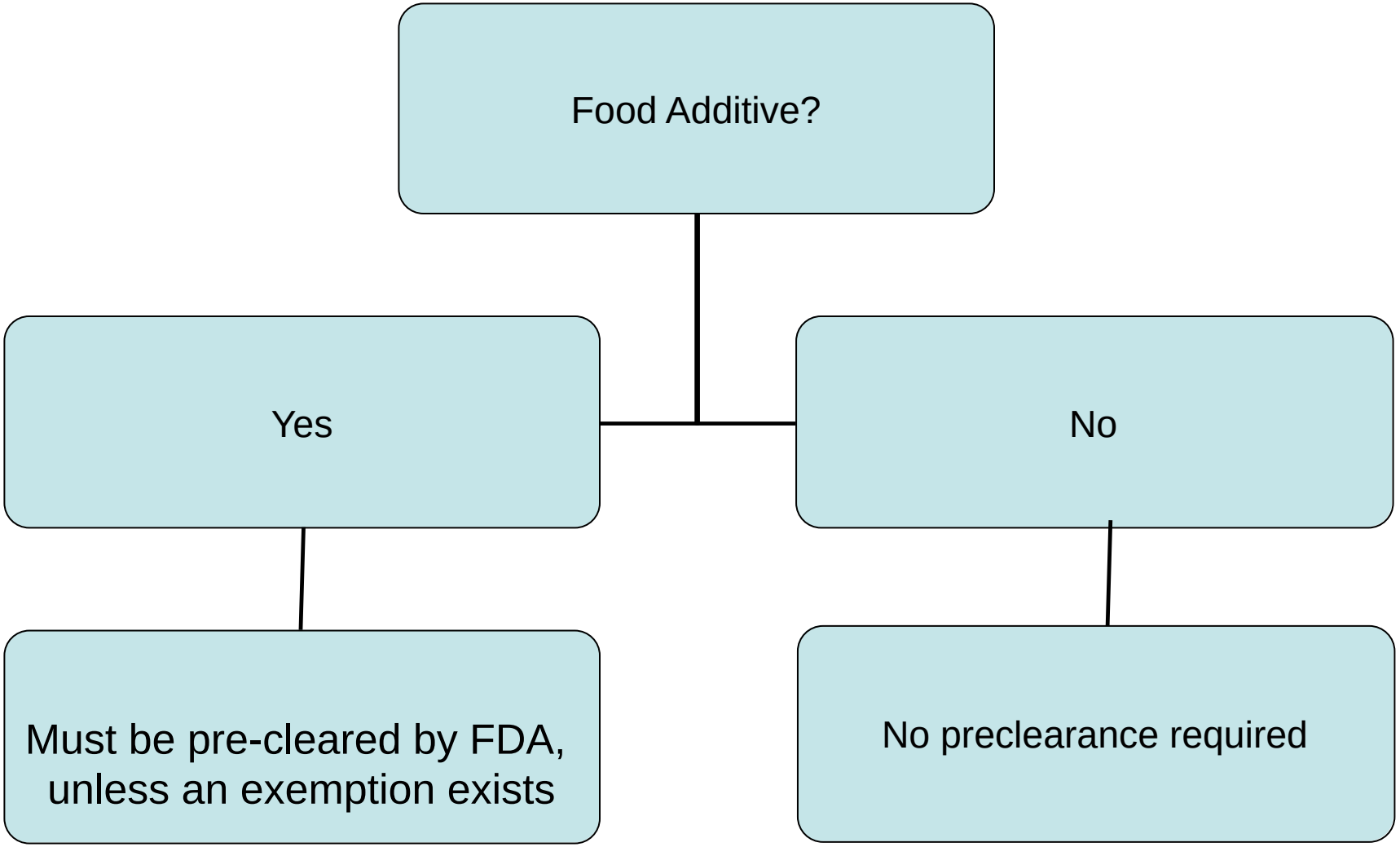
One Type of Additive: “Direct Additives”

- Substances added directly to food AND have a technical effect in or on the food

Another Type of Additive: "Indirect Additives"

- Substances that may become a component of (or migrate to) food BUT are not intended to have a technical effect in or on the food

Regulation of Food Additives

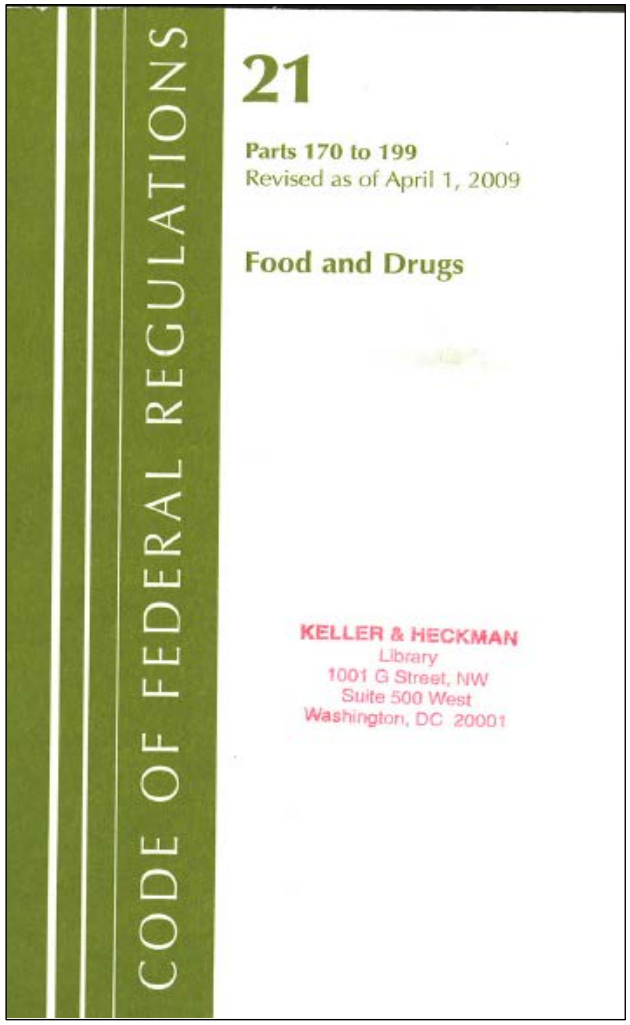


If the substance is a food additive:

It must be subject to a clearance:

- Food Additive Regulation
- Threshold of Regulation
- Food Contact Notification (FCN)

FDA's Food Additive Regulations



CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

(Parts 170 to 199)

EDITORIAL NOTE: Nomenclature changes to chapter I appear at 59 FR 14363, Mar. 28, 1994, and 69 FR 18803, Apr. 9, 2004.

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION (CONTINUED)

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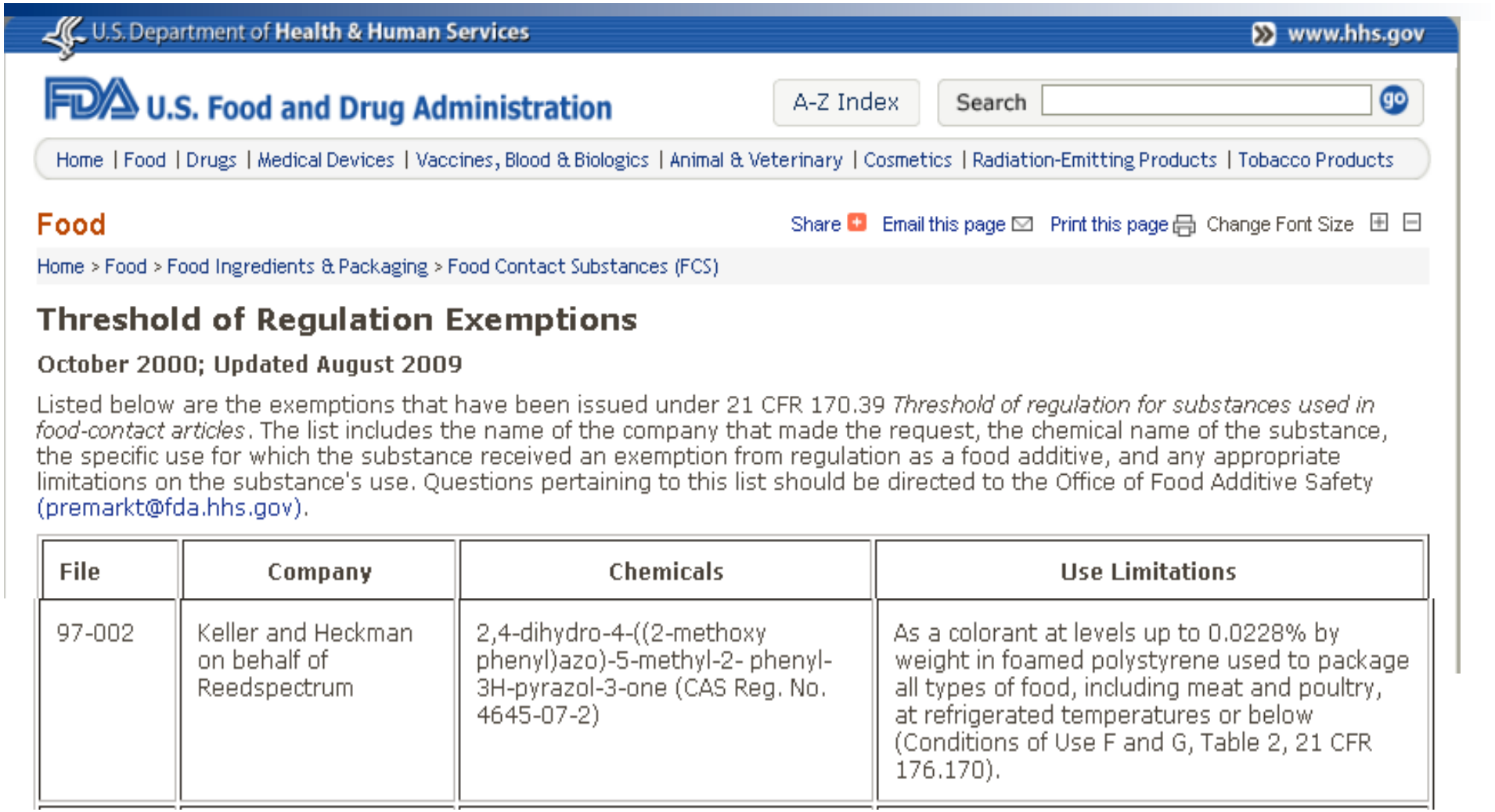
(d) Color additives and their lakes listed for direct use in foods, under the provisions of the color additive regulations in parts 73, 74, 81, and 82 of this chapter, may also be used as colorants for food-contact polymers.

(e) List of substances:

Substances	Limitations
Aluminum.	
Aluminum hydrate.	
Aluminum and potassium silicate (mica).	
Aluminum mono-, di-, and tristearate.	
Aluminum silicate (China clay).	
4-[[5-[[[4-(Aminocarbonyl) phenyl] amino]carbonyl]- 2-methoxyphenyl]azo]-*N*-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-2-naphthalene-carboxamide (C.I. Pigment Red 187, CAS Reg. No. 59487–23–9).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact foods only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
N-[4-(Aminocarbonyl)phenyl]-4-[[1-[[(2,3-dihydro-2-oxo-1*H*-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzamide (C. I. Pigment Yellow 181, CAS Reg. No. 74441–05–7).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
Anthra(2,1,9-def:(6,5,10-d′e′f)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29; CAS Reg. No. 81–33–4).	For use at levels not to exceed 1% by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter.

Threshold of Regulation



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Threshold of Regulation Exemptions

October 2000; Updated August 2009

Listed below are the exemptions that have been issued under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. The list includes the name of the company that made the request, the chemical name of the substance, the specific use for which the substance received an exemption from regulation as a food additive, and any appropriate limitations on the substance's use. Questions pertaining to this list should be directed to the Office of Food Additive Safety (premarkt@fda.hhs.gov).

File	Company	Chemicals	Use Limitations
97-002	Keller and Heckman on behalf of Reedspectrum	2,4-dihydro-4-((2-methoxy phenyl)azo)-5-methyl-2- phenyl-3H-pyrazol-3-one (CAS Reg. No. 4645-07-2)	As a colorant at levels up to 0.0228% by weight in foamed polystyrene used to package all types of food, including meat and poultry, at refrigerated temperatures or below (Conditions of Use F and G, Table 2, 21 CFR 176.170).

Inventory of Effective Food Contact Substance (FCS) Notifications

FCN No. 772

Return to Listing

Food Contact Substance:	A mixture of one or more of tripropylene glycol diacrylate (CAS Reg. No. 42978-66-5), trimethylolpropane triacrylate (CAS Reg. No. 15625-89-5), trimethylolpropane ethoxylate triacrylate (CAS Reg. No. 28961-43-5), and bisphenol A diglycidyl ether diacrylate (CAS Reg. No. 4687-94-9, 53814-24-7, 55127-80-5, 55818-57-0 or 37625-93-7), and optionally the difunctional alpha-hydroxy ketone described in the notification as a photoinitiator. The mixture will be cured by either ultraviolet (UV) or electron beam (EB) irradiation.
Notifier:	Alcan Packaging, Alcoa, Inc., Amgraph Packaging, Inc., Ashland Specialty Chemical Company, Bayer Polymers LLC, Bostik-Findley, Bryce Corporation, Coating and Adhesives Corporation, Crown Cork & Seal, Cytec Industries, Dart Container, Dixie Packaging, Energy Sciences Inc., Fujihunt, Fusion UV Systems, Inc., Gidue SpA, Graphic Packaging Inc., H.B Fuller Company, IGM Resins, INX International Ink Co., Lamberti, s.p.a., Liofol, MeadWestvaco, Nordson Corporation, Petroferm Inc., Pliant Corporation, PPG Industries, Inc., Printpack Inc., Rahn USA Corporation, Rock-Tenn Company, Rohm and Haas Company, Sartomer Company, Sealed Air, Siegwerk Group, Valspar Corporation

Inventory of Effective Food Contact Substance (FCS) Notifications

Intended Use:	To be used as coatings (including inks) or components of coatings (including inks) on polymeric substrates, paper and paperboard, metal substrates, or as a component in adhesives.
Effective Date:	03/08/2008
Limitations/Specifications:	The cured resins may include other substances permitted for the intended use by regulation under 21 CFR. The finished coating, when tested according to the compliance test protocol set forth in the FCN, shall yield a migration level for each monomer and photoinitiator used that is the subject of this FCN that does not exceed 10 micrograms per square inch (ug/in^2) and the total level of nonvolatile extractables derived from the finished coating will not exceed 10 ug/in^2, after correction for the migration levels for each monomer and photoinitiator used. For use in contact with all food types under Conditions of Use A through H, as described in Tables 1 and 2. The food contact articles containing the coatings will meet all applicable regulations under 21 CFR.
Environmental Impact Decisions:	Environmental Decisions Site

Food Additive Exemptions

The U.S. Food, Drug, and Cosmetic Act sets forth the legal requirement that "food additives" must be pre-cleared by FDA

However, in the Act, there are two exemptions:

- If the substance is Prior Sanctioned

OR

- If the substance is generally recognized as safe (GRAS)

Then the substance is <u>not</u> a "food additive"

Prior Sanctioned

- Prior to 1958, companies would ask FDA, informally, for its authorization of a food-contact substance
- If the substance was deemed acceptable (safe) by FDA, the Agency issued a letter to the company and the company would keep the letter in its files
- Under U.S. law, a substance subject to an FDA letter prior to 1958 is considered "**prior sanctioned**" and thus not a "food additive"

The Problem with Prior Sanction

- Most of the letters issued by FDA are so old that they no longer exist. Most were thrown out by FDA!!

- What can you do?

- Look at the "Lehman List" and Part 181 in the Code of Federal Regulations

Caveat: If you have a letter from FDA, or you can rely on a listing in Part 181, you must use the substance within the limitations set forth in the letter or listing

Lehman List

COLORANTS

Many of the resins used in can enamels are colorless in thin films which makes it difficult to distinguish whether or not a particular run of tinplate has been enameled. Coloring of the enamel has been suggested as a means for identifying treated tinplate. Certified FD&C dyes apparently cannot be adapted for this purpose. Several organic dyes not on the certifiable list have been suggested as substitutes. In this instance it is essential to demonstrate that the coloring is not transferred from the film to the food in any amount.

Before giving consideration to any uncertifiable dye there should be available full information setting forth the specific chemical structure of the dye and the complete analysis in terms of the various components and impurities that may be present. On the assumption that the data suggested above do not present any further problem, extraction studies are next in order. A specific and sensitive method for determining the dye must be available, and the leaching effect of simulated food solvents determined. Any demonstrable leaching would rule against the uncertifiable dye as being acceptable as a marker for can enamels. This would also apply to dyes in films for wrapping foods.

Certain pigments have acceptance as colorants for plastic films. These are:

Carbon black
Oxides of iron
Titanium dioxide (National Formulary grade)
Ultramarine blue

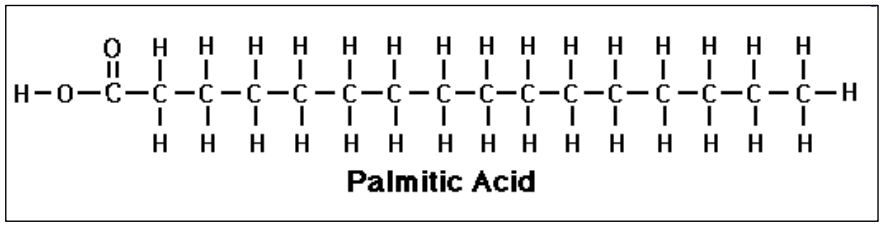
Generally Recognized as Safe (GRAS)

- There are a variety of ways of reaching a GRAS conclusion:
- Commonly used in food prior to 1958
- Scientific procedures
- Listed in GRAS regulations (Parts 182, 184, and 186)

Generally Recognized as Safe (GRAS)

- Commonly used in food prior to 1958

- Palmitic acid



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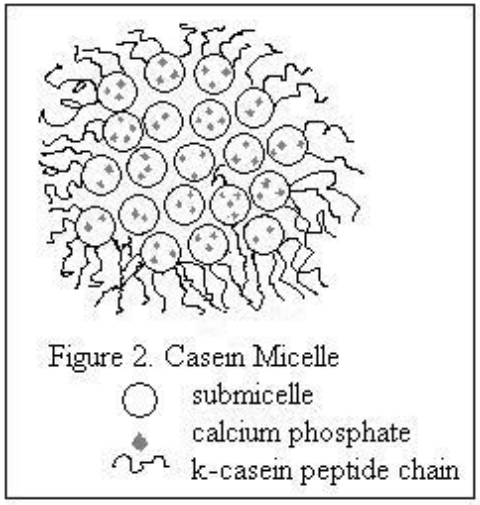
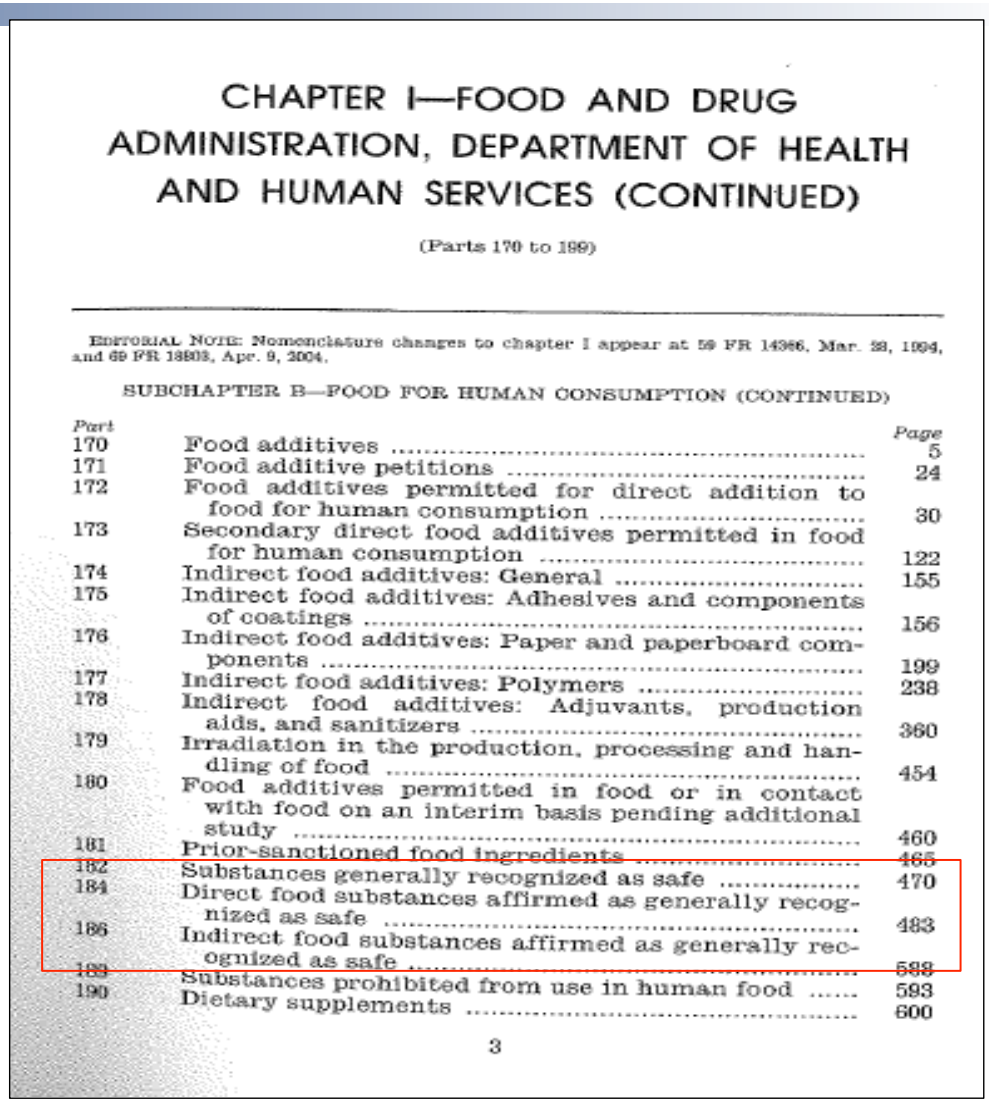


Generally Recognized as Safe (GRAS)

- If not commonly used in food prior to 1958, then you can rely on scientific procedures:
- Must show consensus of experts (general recognition) deem substance to be safe, based on published safety data

Generally Recognized as Safe (GRAS)

- Some GRAS substances listed in regulations (Parts 182, 184, 186)



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SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION (CONTINUED)

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Other Exemptions: No Migration

What if the substance is NOT:

- GRAS
- Prior Sanctioned

- Remember: If the substance is not reasonably expected to become a component, it is not a "food additive" under the law and FDA premarket clearance is not required.

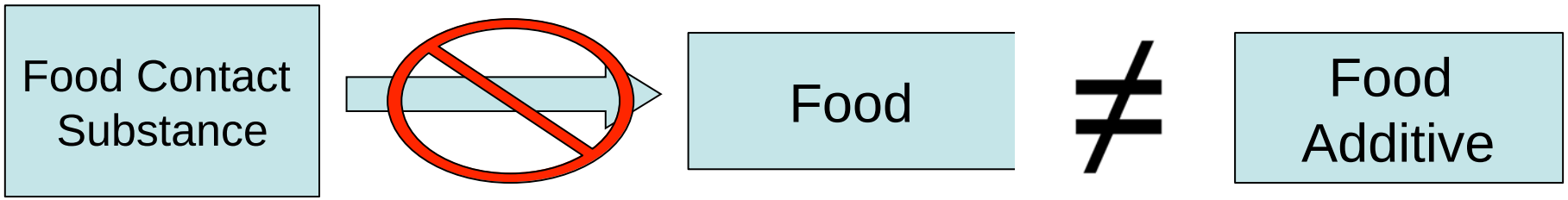
- So, if a substance doesn't migrate to food under the intended conditions of use, you can legally market the substance by taking what is commonly referred to as:

A "No Migration – No Food Additive" Position

No Migration – No Food Additive

There is U.S. case law to support a "No Migration – No Food Additive" position:

Monsanto v. Kennedy: FDA must find a substance migrates into food in more than insignificant amounts to consider it a food additive



Functional Barrier

- Substances separated from food by a barrier that prevents their migration to food are not properly considered to be “food additives”

Remember Suitable Purity!

Section 174.5(a)(2) of FDA's regulations:

- "Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use."

- So, even if your substance is otherwise cleared by FDA (e.g., subject to a food additive regulations or FCN), it must still be suitably pure for the intended use

Section 174.5 – Suitable Purity

- Packaging must not cause food to be:
  - Unsafe
  - Unfit for consumption (*i.e.*, affect the organoleptic properties of the food)
    - Taste
    - Smell
    - Appearance

FDA's Regulation of Printing Inks used in Food Contact Materials

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Printing Inks

- Inks used to print food on packaging materials are considered “colorants” by FDA, i.e., potential “food additives”

- Colorants used in food packaging are not considered “color additives” (see 21 CFR 70.3(f)) unless they impart color to food that is visible to the naked eye

Printing Inks

- Inks, overlaquers, primers, solvents or any other substance in a printing ink system for food packaging are evaluated as any other packaging component

- Is there a reasonable expectation that the ink or its components could migrate to food?

Printing Inks

- If ink component "may reasonably be expected to migrate to food," then options are our standard ones:
  - Regulatory clearance under parts 170 – 179;
  - GRAS position based on listings, toxicity data or low exposure;
  - Prior sanctioned;
  - TOR exemption letter; or
  - Applicable Food Contact Notification

Printing Inks

- Unlike coatings and adhesives, there is no FDA regulation that specifically clears inks used in food packaging

- However, many ink components are found in
  - 21 CFR 178.3297 (“Colorants for polymers”) or,
  - 21 CFR 176.170 (“Components of paper and paperboard in contact with aqueous and fatty foods”) if used in paper applications
  - Stand-alone regulations such as 21 C.F.R. 177.1520 (“Olefin polymers”) (for polyolefin carrier)

Printing Inks

- Many inks are on the market based on existence of a functional barrier between the ink and food

- As always, potential for migration depends on:
  - MW and concentration of ink component,
  - Type/thickness of material separating food from ink,
  - Type of food, and
  - Duration and temperature of exposure

Printing Inks – Offset Issues

- Be aware of offset of inks from rolled or stacked packaging material:
- Ink from the printed exterior of a package transfers to food contact side during the storage and handling of the packaging material
- GMP issue
- Monitoring and assessment needed to avoid contamination

Resources for you…

- FCN Inventory: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing&displayAll=true
- GRAS Notice Inventory: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing
- TOR Inventory: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm093685.htm

Resources for you…

- FCN Administrative Guidance: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081807.htm
- FCN Chemistry Guidance: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm
- FCN Toxicology Guidance: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm

Thank you

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