

Regulatory Analysis of U.S. Food Contact Material Legislation



Name: Aaron Cheng
Title: FCM Business Manager



Europe | India | South Korea | Eurasia | Turkey | UK | Taiwan | Australia | Ireland

1

CONTENT

01

Food Contact Material and Food Safety

02

U.S. Food Contact Material Regulatory System

03

Corporate Compliance Obligation



2

PART 01

2022-06-16
©Global Product Compliance – GPC

Food Contact Material and Food Safety

3

3

Food Contact Material (FCM)



Definition

- Intended to come into contact with food or already in contact with food
- Includes both food packaging and other materials or components, e.g. parts of food processing equipment
- Coffee makers, production machines, containers used for transport in the food industry

4

4

Safety of Food Contact Materials



PFAS & mineral oil in hamburger paper



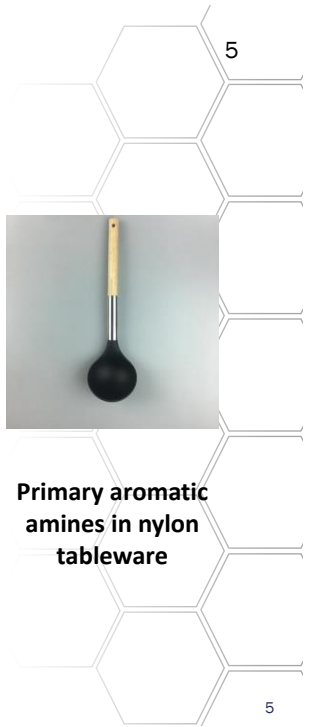
Plasticizer in PVC cling film



BPA in PC bottles



Primary aromatic amines in nylon tableware



5

6

PART 02

U.S. Food Contact Material Regulatory System

6

6

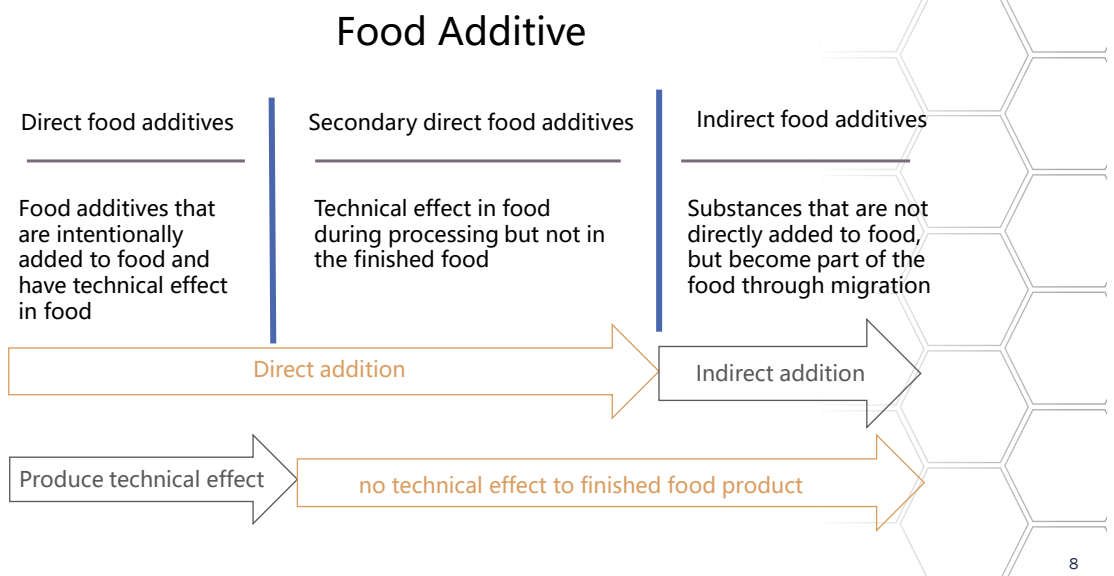
Definition of Food Additives

Section 201 (s) of the FD&C:

“**food additive**” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use)

7

Types of Food Additives

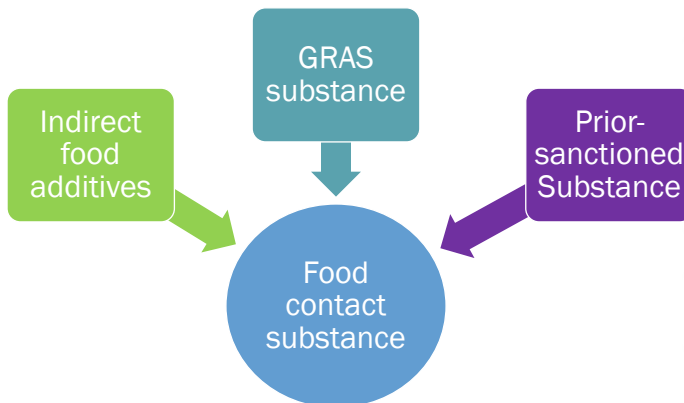


8

Definition of Food Contact Substance

Food Contact Substance (FCS) - Section 409 of the FD&C Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.

➤ This can be a monomer, or polymer or additives.

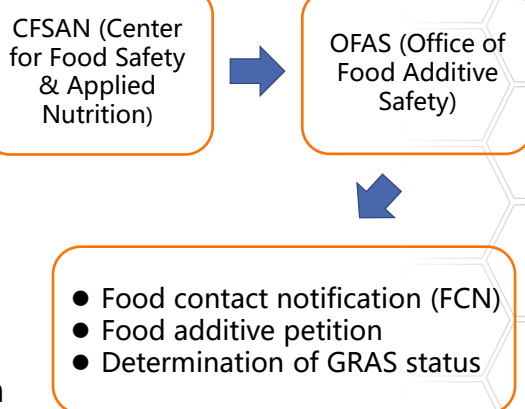


9

Competent Authorities



Food and Drug Administration (FDA)



10

10

Regulatory framework of the FCM in the U.S.

Federal Food, Drug and Cosmetic Act

- Allow FDA to approve new food additives
- Sec. 201 (Package defined), Sec. 301 (Prohibited acts), Sec. 409 (Food additives)

Code of Federal Regulation Title 21 (21 CFR) (174-186)

- Part 174 Indirect food additives: General
- Part 175-178 Specific measures for adhesives, coatings, paper & board, polymers, adjuvants, production aids and sanitizers
- Part 182-186 Substances affirmed as generally recognized as safe (GRAS)

Compliance Policy Guides – CPG

- The CPG guidance involving food contact material include FDA CPG Chapter 5, which sets the relevant limit index requirements for the dissolution of lead and cadmium in imported silver-plated tableware/ ceramic products, and specifies the detection methods for the dissolution of lead and cadmium

California Proposition 65

- Some state legislatures have enacted a series of regulations involving food packaging under the category of food safety and hygiene. Therefore, while paying attention to the laws and regulations on food contact materials formulated by the federal government, we should also pay attention to the specific laws and regulations formulated by various states for different types of food contact materials

Fundamental requirements

Specific measures

Special products

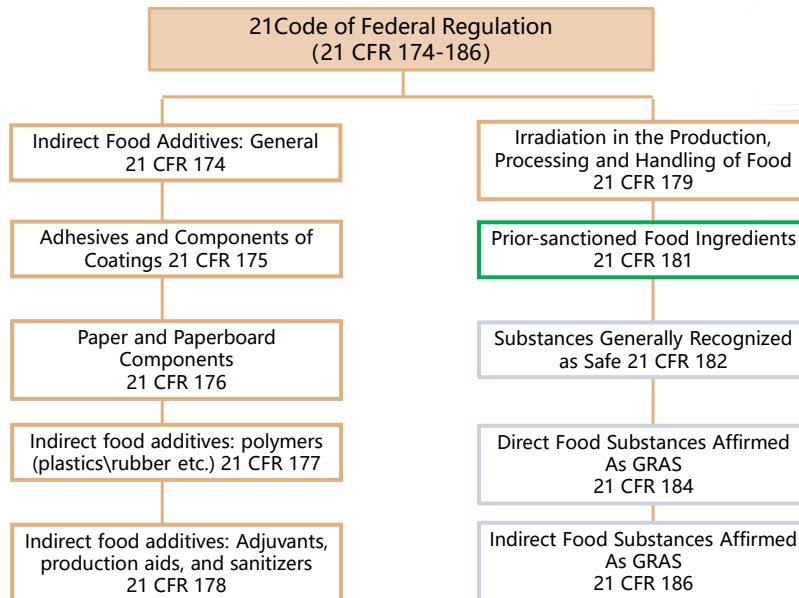
State level legislation

11

11

11

21Code of Federal Regulation (21CFR)



12

12

12

13

GRAS, generally recognized as safe

1. "GRAS" is an acronym for the phrase Generally Recognized As Safe.
2. Substances used in food before 1958, through experience based on common use in food Under 21 CFR 170.30(b).
3. General recognition of safety through scientific procedures is based upon a large number of publicly available scientific data and may be corroborated by the application of unpublished scientific data, information, or methods

21CFR § 182, § 184, § 186

21CFR § 181

Prior-sanctioned substances

1. Substances were explicitly approved by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958
2. The substances listed in 21CFR §181

13

13

General Provisions of Food Contact Substance in 21CFR

1. **Any use of food contact substance must be permitted by FDA**
2. The production of food contact substance should comply with Good Manufacturing Practice (GMP)
3. Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.
4. The use level should not exceed the quantity reasonably required to accomplish the intended physical or technical effect in the food contact articles.
5. Food contact substance and material should subject to any prescribed limitation in 21CFR.

14

14

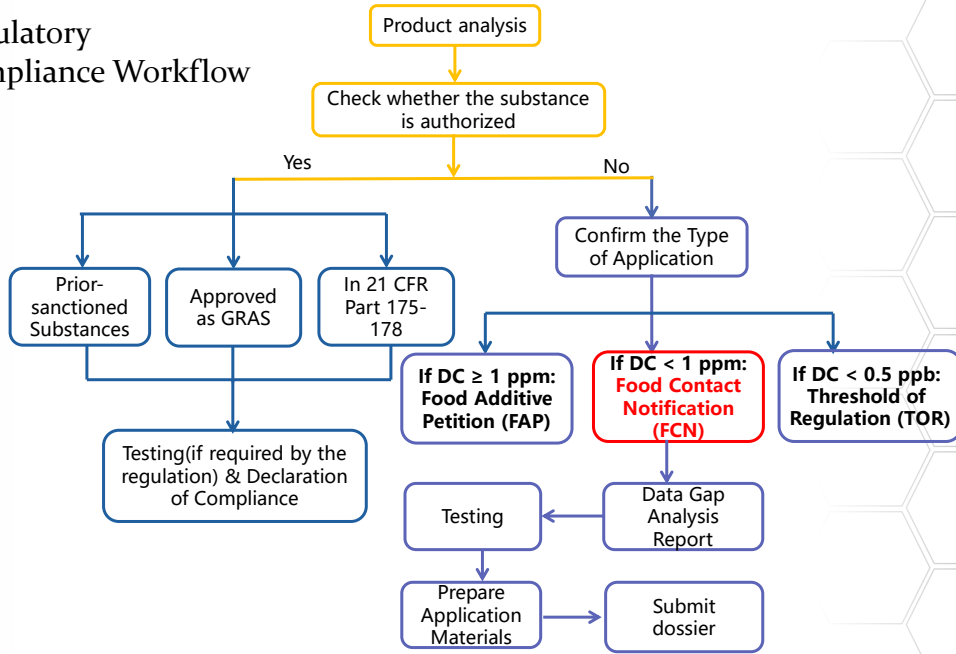
14

PART 03

Corporate Compliance Obligation

2022-06-16
©Global Product Compliance – GPC

Regulatory Compliance Workflow



Compliance Testing and Declaration of Compliance(DoC)

➤ Authorized Substance----- **Compliance Obligation**



1. Compliance Testing (If required by the regulation)

2. Declaration of Compliance

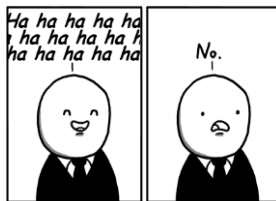
- Substance Basic Information
- Substance Regulatory Status
- Terms of Use
- Testing Result (if required by the regulation)

17

17

What is a new food contact substance?

Substance listed in the positive list =? = allowed for use



New substance! ! !



1. Whether listed in the corresponding positive list (paper and paperboard? Coatings? Adhesives?)
2. Whether the identification conditions of the substance are met? (If required)
3. Whether the use conditions of the substance are met? (Usage amount, Use time/temperature conditions, Type of food contacted)

18

18

18

Food Contact Notification (FCN) application

- An FCN approval is **proprietary to the manufacturer/supplier**
- The office of food additive safety (OFAS) in FDA' s Center of food safety and applied nutrition is responsible for the evaluation of the documents

Who may submit an FCN?

- A manufacturer or supplier of an FCS may submit to FDA a notification for a new use of an FCS
- The term supplier means any person supplying the FCS, including companies supplying the FCS to themselves for the manufacture of a food contact material

19



Food Contact Notification (FCN) application

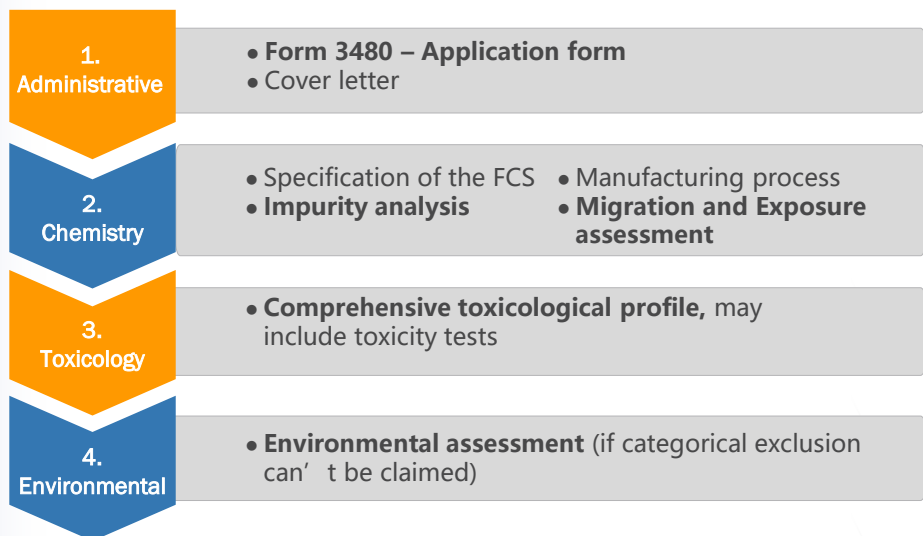
When should an FCN be submitted?

- FCNs are required only for new uses of food contact substances
- Examples:
 - New (unapproved) FCS
 - New uses of approved FCS (e.g. higher temperature)
 - New manufacturing process and impurities of already notified FCS and uses
 - Same notified FCS and use but manufactured by a different manufacturer or supplied by a new distributor/supplier

20



Data requirements for an FCN



21

21

21

Toxicological data requirements

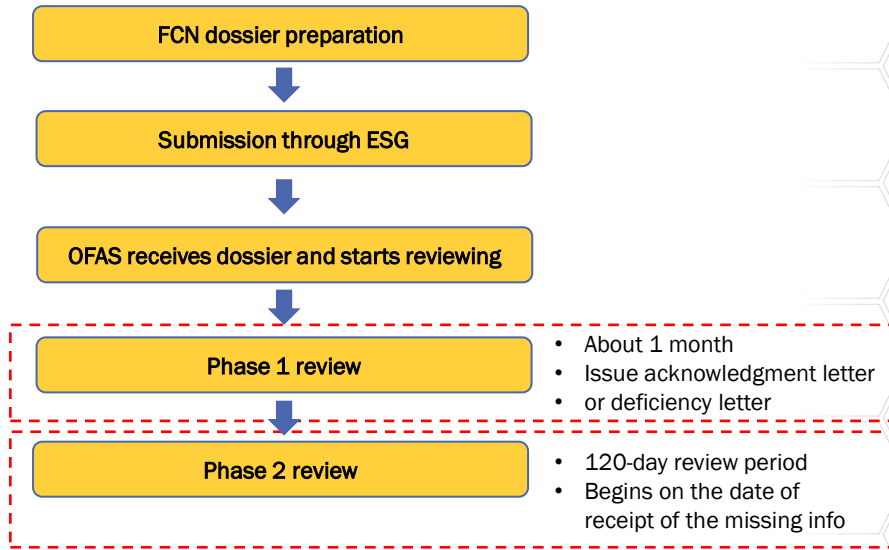
Category	Exposure level (DC)	Toxicological data requirements
Tier 1	≤ 0.5 ppb	<ul style="list-style-type: none"> • No safety studies are recommended • Lifetime cancer risk for carcinogenic components should be assessed
Tier 2	0.5 ppb – 50 ppb	<ul style="list-style-type: none"> • At least 2 genetic toxicity tests • Lifetime cancer risk for carcinogenic components should be assessed
Tier 3	50 ppb – 1 ppm	<ul style="list-style-type: none"> • At least 2 genetic toxicity tests • In vivo chromosomal damage test • Rodent subchronic toxicity study
Tier 4	≥ 1 ppm	<ul style="list-style-type: none"> • Food additive petition is recommended

22

22

22

FCN review process



23

23

23

Our Services



24

24

24

Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



Global Product Compliance (GPC)



compliance@gpcregulatory.com



+46 46 2114615



IDEON, Beta 5, Scheelevägen 17, 22363
LUND, SWEDEN