Acknowledgement and Disclaimer:

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Determining the Regulatory Status of Components of a Food Contact Material

The overall regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. The individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material shall be covered by one of the following:

- a regulation listed in Title 21 Code of Federal Regulations
- a prior sanction letter
- meeting the criteria for GRAS status (including but not limited to a GRAS regulation or GRAS notice)
- a Threshold of Regulation (TOR) exemption request
- or an effective Food Contact Notification (FCN).

Be aware that Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) states that an FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification and not effective for a similar or identical substance produced or prepared by a manufacturer other than a manufacturer identified in the prior notification. FCNs are proprietary to the manufacturer for which the notification is effective, therefore, the FCS must be obtained from that manufacturer.

It is the **responsibility of the manufacturer** of an FCS to ensure that food contact materials comply with the specifications and limitations in all applicable authorizations. When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties and *limitations* on the conditions of use.

You may ask the manufacturer for a letter of guaranty[1] to customers (Section 303(c)(2) of the act) certifying that a particular product is acceptable for the intended food-contact use.

TECHNICAL AND BUSINESS SERVICES, LLC
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How do I determine the compliance of the components of my food contact article with the requirements of the act?

There are a number of ways that a component of your food contact article may comply with the act. The table below is designed to help you make that determination. The table below allows you to research each component for category of authorization.

Consult 21 CFR 174-179 to see if the use of the component is an appropriately regulated indirect additive.	Consult 21 CFR 182-186 to see if the use of the component is Generally Recognized as Safe (GRAS)* or consult the list of GRAS Notices
Consult 21 CFR 181 to see if the use of the component is Prior Sanctioned*	Consult the listing of Threshold of Regulation Exemptions
Consult the listing of Effective Food Contact Substance Notifications	

If any component of my food contact article is not covered by any of the categories above, what options do I have?

Submit a Threshold of Regulation Exemption Request[2]	Or ↔	Submit a Food Contact Substance Notification[3].	Or ↔	Satisfy the criteria for GRAS status[4]

- **Consult 21 CFR 174-179 to see if the use of the component is an appropriately regulated indirect additive.**
  - General Indirect Food Additives (21 CFR 174[5])
  - Adhesives and Components of Coatings (21 CFR 175[6])
  - Paper and Paperboard Components (21 CFR 176[7])
  - Polymers (21 CFR 177[8])
  - Adjuvants, Production Aids, and Sanitizers (21 CFR 178[9])
  - Irradiation in the Production, Processing and Handling of Food (21 CFR 179[10])

The requirement for premarket approval in section 409[11] of the FD&C Act in 1958 resulted in the development of a petition process by which a person could request approval of a food additive for an intended use. The approval resulted in a regulation listed in 21 CFR. Components of a food packaging

material used in compliance with a regulation in 21 CFR (174-179) need no further FDA review. Most of the regulated indirect food additives can be found in CFSAN's "Indirect Additive" Database

Consult 21 CFR 182-186 to see if the use of the component is listed as Generally Recognized As Safe (GRAS).*

- Substances GRAS in food (21 CFR 182[12])
- Substances affirmed as GRAS in food (21 CFR 184[13])
- Substances affirmed as GRAS for use in food packaging (21 CFR 186[14])

Not all substances which are GRAS are listed in FDA's regulations. FDA has instituted a procedure whereby someone may inform FDA of their own GRAS determination. A list of these GRAS notices, with FDA's response letter to the notifier, is also available at "Summary of all GRAS Notices[15]."

- **Consult 21 CFR 181[16] to see if the use of the component is listed as Prior Sanctioned.***

Prior Sanctioned substances are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.

- **Consult the listing of Threshold of Regulation Exemptions[17] to check if the component is exempted from a petition or an FCN as a food additive because it becomes a component of food at levels that are below the threshold of regulation.**

A substance used in a food contact article may be exempted by FDA from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb). For details see, "Submitting Requests Under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles."

- **Consult the listing of effective Food Contact Substance Notifications[18].**

The listing of effective food contact substance notifications, the regulation, guidance documents[19], and additional information regarding the notification program are listed the Food Contact Substance web page. However, you should be aware that FCNs are proprietary and users must be able to trace the substance they use back to the manufacturer for which the notification is effective.

- **Submit a Food Contact Formulation (FCF) Notification.**

Occasionally, individuals may wish to verify compliance of the components of a particular food contact material. In such instances they may submit a notification for a food contact substance formulation. The purpose of a formulation notification is to verify that components of a food contact material may legally be used and not to authorize a new food contact substance. Because these notifications are for the purpose of regulatory status and not safety assessments, notifications for formulations do not require resubmission of the information supporting the safety of the intended use of each food contact substance in the formulation. A notifier for a formulation need only submit a completed FDA Form 3479[20] and any additional documentation required to establish that each of the components of the formulation is authorized for its intended use. In cases where the basis for compliance of an individual FCS in a formulation is an effective

notification, a notifier of the formulation should establish that he can rely on the notification cited for the intended use of the FCS in the formulation.

* Not all uses of substances that are GRAS are listed in Title 21, covered by a GRAS notification, or listed as a prior-sanction. Therefore, you may wish to specify the types of materials you are interested in and we will check our files for information on the regulatory status of these substances.

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