

Food Contact and Food Additive Compliance

Domestic (FDA) and International Regulations

ARCADIS is well versed in handling the regulatory, toxicology, chemistry and agency liaison needs for manufacturers of food contact materials, food additives, and related substances.



In this era of changing regulations and international harmonization, ARCADIS offers expertise associated with the labyrinth of US regulations for direct and indirect food additives. These regulations are fragmented and many historical decisions, such as prior sanction and letters of opinion, are not easily accessible or immediately available to the general public. Our historical knowledge of the regulations and decisions allows us to quickly navigate to the most knowledgeable decision makers within the agency and work through the process to reduce time to market.

ARCADIS is well versed in handling the regulatory, toxicology, chemistry and agency liaison needs for manufacturers of food contact materials, food additives, and related substances. Our expertise allows for a streamlined approach that minimizes and expedites data submissions, bringing products to market in a reduced time frame. Our knowledge of the regulations and daily interaction with FDA officers and reviewers allows

your company to take the inside track to regulatory decision making. Our in-depth experience includes, but is not limited to the following:

- GRAS Determinations and Affirmations
- Food Additive Petitions
- Food Contact Notifications
- Threshold of Regulation Exemptions
- New Dietary Ingredient (NDI) Notifications
- International Guidelines and Directives

ARCADIS can summarize data requirements, interpret your data set, coordinate data development where gaps exist or obtain data waivers, prepare your submission, and facilitate discussions with FDA.

We are comfortable in handling the entire data package development and submission to FDA or any smaller portion where you need an experienced partner.

ARCADIS offers formulary consulting and supplier sourcing, compliance evaluations, risk assessment, and regulatory submission services required for marketing food additives, and food contact materials. Specific services include:

- Formulary and Data Reviews to confirm compliance with the United States Code of Federal Regulations: Title 21 Food and Drugs (21CFR)
- Formulary consulting to develop compliant products
- Supplier sourcing
- Recommendation and contracting with appropriate laboratory to conduct extraction, leachables analyses, and purity testing to confirm compliance with 21CFR limitations; migration testing to determine extractables associated with a new food contact material or a new use of a current material
- Agency liaison, correspondence and protocol development for new and historical technologies
- Toxicological testing recommendations, testing coordination and oversight.
- Toxicological risk assessment dossiers in support of substance/product safety determination

- Regulatory strategy development and determination of the most cost efficient means to meet regulatory compliance
- Risk assessment, cumulative estimated daily intake, acceptable daily intake, recommended daily intake calculations
- Material characterization
- Coordination and compilation of entire substance-specific dataset into formal submission documentation
- “Me too” submissions

Our success is measured by streamlining and reducing your time to market focusing on minimizing costs and cost avoidance. ARCADIS staff members have over 30 years of successful FDA, EPA, and USDA collaboration developed through partnership and positive interaction.

We use a team approach where the client is an involved partner in a successful regulatory outcome.

ARCADIS staff have had success in reducing the time to market from three years to two weeks through successful discussions with the appropriate regulatory decision makers.

For more information:

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