Indirect Food Contact & Material Selection for Mechanical Seals in Food Processing

A U.S. FDA compliance and materials-selection guide.

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ACRONYMS & DEFINITIONS

Acronym	Full Name/Meaning	Relevance
FDA	Food and Drug Administration	Primary U.S. federal agency regulating food contact substances and materials
FFDCA	Federal Food, Drug and Cosmetic Act	U.S. law defining food additives, including indirect food contact substances that may migrate into food
FCS	Food Contact Substance	Any substance intended for use in materials that contact food; requires FDA review unless exempt
FCN	Food Contact Notification	Primary FDA premarket clearance pathway for new food contact substances used in equipment or packaging
CFR	Code of Federal Regulations	Codified U.S. federal rules, including Title 21, which covers food contact materials
21 CFR 177.2600	Rubber Articles Intended for Repeated Use	Key regulation defining extraction limits for rubber materials used in mechanical seals and other food processing components
TOR	Threshold of Regulation Exemption	FDA exemption pathway when migration exposure is extremely low and presents negligible risk
CIP	Clean in Place	Sanitation method relevant to seal design; affects material durability
3 A	3 A Sanitary Standards	U.S. voluntary hygienic design standards for food processing equipment
EHEDG	European Hygienic Engineering & Design Group	EU hygienic design consortium providing cleanability standards

Ensuring the safety and integrity of food during processing requires careful attention to all components that may come into indirect contact with food, including mechanical seals used in pumps, mixers, homogenizers and other moving equipment. While these seals do not intentionally touch food, according to regulatory agencies, any material that may reasonably migrate into food falls under "indirect food contact" requirements. Failure to select compliant materials can result in contamination risks, regulatory violations, equipment inefficiency and costly recalls.

This article outlines the regulatory landscape of indirect food contact, identifies key considerations for selecting compliant seal materials and provides a framework for engineering decision making.

What Is Indirect Food Contact?

Indirect food contact refers to materials that do not physically touch food but may still transfer chemical components into the food supply during processing, packaging or storage. Such migration can occur via vapors, lubricants, polymers, adhesives, coatings or mechanical components such as seals. Regulatory agencies classify any substance reasonably expected to become a component of food as a food additive unless explicitly exempted (FFDCA).

Migration assessment is at the core of indirect food contact regulations, as even very low level transfer is regulated. The FDA governs indirect food additives through multiple pathways including FCNs, food additive regulations and TOR exemptions.

Regulatory Framework for Indirect Food Contact Materials

FDA regulations (21 CFR 174–178)

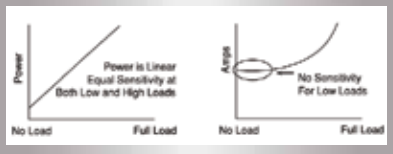
The FDA regulates substances used in food processing equipment via rules covering polymers, adjuvants and production aids (21 CFR 174, 177, 178). These regulations specify allowable compositions, extractables, conditions of use and temperature limits for wetted surfaces in food processing equipment.

Mechanical seal specific standards

Three primary frameworks govern mechanical seals in food and beverage:

1. **FDA 21 CFR 177.2600** defines maximum extractable matter for rubber compounds under water and hexane extraction conditions. Acceptable extraction levels differ dramatically based on food type. For example, aqueous foods permit less than or equal to 20 milligrams per square inch (mg/in²) extraction versus less than or equal to 175 mg/in² for fatty foods under the same conditions.
2. **3 A Sanitary Standard 18 03** focuses on hygienic equipment design.
3. **EHEDG Guideline 25** evaluates cleanability performance.

Many engineering specifications incorrectly assume "FDA compliant seals"

PROTECT PUMPS
DRY RUNNING • CAVITATION • BEARING FAILURE • OVERLOAD
Monitor Pump Power
• Best Sensitivity
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• Relay Outputs
• Adjustable Delay Timers
4-20 Milliamp Analog Output
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• Raceway • Wall
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apply universally, but the standards serve distinct purposes, and misuse leads to compliance failures.

How Indirect Food Contact Affects Mechanical Seal Material Selection

Mechanical seals in food processing equipment face challenges including temperature extremes, chemical exposure, pressure fluctuations and strict sanitation requirements. Thus, selecting materials that are simultaneously regulatory compliant, chemically compatible, mechanically durable and cleanable is essential.

Material categories and compliance

To meet regulatory requirements, materials must be safe for indirect food contact and demonstrate minimal extractables. FDA compliant compounds include stainless steel, silicone and specific rubber formulations designed to resist both chemical and thermal degradation in food environments.

Further, rubber materials used in seals fall into types (A D, A E, A F) based on the intended food category (dry, aqueous/acidic or fatty) and temperature limits. Misalignment between material type and food application often leads to noncompliance during audits or testing.

Key Factors in Selecting the Right Mechanical Seal Materials

The following engineering considerations are essential when specifying a mechanical seal for food processing equipment:

1. ***Regulatory compliance:*** Seal materials must satisfy applicable FDA sections and extraction requirements, supported by documentation verifying intended use. Manufacturers must demonstrate that seals resist migration and chemical leaching under normal operating conditions.
2. ***Chemical compatibility:*** Food products contain acids, oils, fats and solvents. Seal materials must resist these reactants to prevent degradation and contamination. For example, acidic products degrade certain elastomers, while high fat foods accelerate plasticizer migration in rubber.
3. ***Temperature resistance:*** Food processing commonly exposes seals to subzero storage conditions and high heat processes such as pasteurization. Materials such as silicone withstand extreme temperatures while maintaining mechanical integrity, making them suitable for dynamic sealing applications.
4. ***Mechanical durability:*** Flexibility, elasticity, compressive strength and wear resistance directly influence seal reliability. Stainless steel and high performance elastomers provide durability in equipment requiring frequent cleaning, exposure to CIP chemicals and high mechanical loading.
5. ***Hygiene and cleanability:*** Standards such as 3 A and EHEDG ensure seals do not harbor biofilms and can be fully sanitized. Designs that incorporate crevice free geometry and smooth surfaces improve cleanability and reduce risk of microbial contamination.

Recommended Materials

Based on regulatory requirements and field performance, commonly accepted materials include:

- **Stainless steel:** High corrosion resistance, hygienic surface; ideal for dairy and beverages
- **Silicone elastomers:** Flexible, temperature resistant, nonreactive; ideal for dynamic seals in both hot and cold applications
- **Food grade rubber (ethylene propylene diene monomer [EPDM], fluoroelastomer [FKM], nitrile butadiene rubber [NBR] variants):** Must meet extraction levels per FDA 177.2600 and be matched to the specific food type

Material selection must be guided by the food type (aqueous, fatty, acidic),

processing temperatures, cleaning regimes and equipment operation profile.

Indirect food contact regulations impose stringent requirements on materials used in food processing equipment—even when contact is incidental. Mechanical seals represent a critical control point due to their chemical exposure, dynamic function and potential for migration. Selecting the right materials requires comprehensive understanding of FDA regulations, extraction limits, chemical compatibility, operating conditions and hygienic design standards.

Engineering teams should avoid generic "FDA compliant" specifications and instead reference the exact CFR sections, food categories and performance conditions relevant to each application. Doing so ensures safety, regulatory compliance, equipment reliability and consumer protection. ■

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We invite your suggestions for article topics as well as questions on sealing issues so we can better respond to the needs of the industry. Please direct your suggestions and questions to sealingsensequestions@fluidsealing.com.

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