Selecting Seals for Indirect Food Contact

A global regulatory and materials selection guide for mechanical seals.

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Mechanical seals in pumps, mixers and fillers are often "indirect food contact" components—parts not intended to touch food, yet capable of transferring trace substances through migration. Globally, regulators treat any material reasonably expected to become a component of food as a regulated food-contact substance, requiring premarket clearance, compliance with positive lists, migration limits and good manufacturing practices (GMP).

For seals, this means specifying not just Food and Drug Administration (FDA) compliance but the exact jurisdictional basis (e.g., 21 Code of Federal Regulations [CFR] section, European Union [EU] Declaration of Compliance [DoC] against 1935/2004 and 10/2011, China's General Safety Requirements [GB] 4806 sub-standard), the food type (aqueous, acidic, fatty), temperature/use conditions and hygienic design requirements (3-A Sanitary Standards/European Hygienic Engineering and Design Group [EHEDG]).



IMAGE 1: Food processing plant (Image credit: zhu difeng- stock.adobe.com

1 Indirect Food Contact: Concepts & Risks

Indirect contact covers materials that hold or process food and may transfer constituents via migration—even at very low concentrations.

Under U.S. law, such substances are "food additives" unless exempted (e.g., through Threshold of Regulation or Generally Recognized As Safe [GRAS]) and typically require a Food Contact Notification (FCN) or other authorization for the specific intended use. The burden of proof sits with the manufacturer/supplier.

For mechanical seals, the main risk is chemical migration from elastomers, plastics, lubricants or coatings—exacerbated by heat, fat, acidity and cleaning chemicals.

Mislabeling a seal as merely FDA-compliant without citing the correct section, extraction test or food category is a common compliance gap.

2 United States (FDA): Framework, Tests & Relevance to Seals

Regulatory pathways

- 21 CFR 174-178 governs indirect additives (polymers, adjuvants, production aids) used in equipment and packaging; compliance must reflect conditions of use (temperature, food type, repeat vs. single use).
- FCN is the primary premarket route; Threshold of Regulation exemptions may apply to negligible exposure; both are use-specific.

Rubber articles for repeated use

- 21 CFR 177.2600 defines extraction limits for rubber, with markedly different limits for aqueous vs. fatty food simulants (e.g., water 20 milligrams per square inch (mg/in²) vs. Hexane 175 mg/in² during the first seven hours) and categorizes rubber types (A-D/E/F) by food class and temperature. Seal specs must match the intended food category and cleaning regimes.

Mechanical-seal takeaway

U.S. compliance requires matching elastomer type and extraction testing to the product's food class, plus documentation of the exact CFR section (not just "FDA-grade rubber").

3 European Union: 1935/2004, GMP, Plastics & Documentation

Framework regulation

- *Regulation (EC) No 1935/2004:* All food-contact materials (FCMs) must be sufficiently inert to prevent harmful transfer and unacceptable changes in composition, taste or odor; scope includes direct and indirect contact.
- *GMP Regulation (EC) No 2023/2006:* Requires controlled manufacturing, quality assurance/quality control (QA/QC) systems and suitable starting materials across the FCM supply chain.

Specific measures & 2025 updates

- *Plastics (EU) No 10/2011:* Union List, specific migration limits (SMLs), overall migration; requires a DoC for harmonized materials. Recent amendments in 2025 refined definitions, purity (including nonintentionally added substances [NIAS] approach), labeling and recycled plastics interfaces. Amendments became effective March 16, 2025.
- EU authorities continue to tighten controls on substances (e.g., Bisphenol A [BPA] restrictions) and align recycled-plastics and GMP expectations.

Mechanical-seal takeaway

For elastomeric or plastic seal elements, EU buyers typically require a DoC referencing 1935/2004, applicable specific measures (e.g., 10/2011 if plastic components are present), GMP 2023/2006, migration test reports with relevant food simulants/time/temperature and traceability. Hygienic design expectations often incorporate EHEDG or 3-A concepts even though they are not EU law.

4 China: GB 4806 Series, Positive Lists & Recent Revisions

China's FCM system is anchored in GB 4806.1, GB 9685 (additives positive list) and material-specific standards (e.g., plastics, metals, rubbers), supported by GB 31603 (GMP) and the GB 31604 test methods for migration. The National Health Commission (NHC) regularly updates standards and positive lists.

Notable recent changes relevant to seal materials

- GB 4806.7-2023 (plastics) and GB 4806.9 2023 (metals) with implementation on Sept. 6, 2024; updates included expanded scope, additive controls via GB 9685 and added alloy element migration limits for metals.
- GB 4806.15-2024 (adhesives) was China's first national standard for food contact adhesives—effective Feb. 8, 2025—with "not detected" (ND) limits for primary aromatic amines (PAAs) and labeling of direct vs. indirect contact categories.
- 2025/2026 updates include new GB 4806.10-2025 (coatings) and GB 4806.16-2025 (silicone rubber) with a 2026 implementation timeline for product standards.

Mechanical-seal takeaway

When specifying seals for China, align materials to the correct GB 4806 part (e.g., silicone rubber once GB 4806.16-2025 is in force), verify additives against GB 9685, perform GB 31604 migration testing under the intended conditions and maintain DoC and labeling per GB 4806.1.

5 Japan: Positive List for Resins & Transition Milestones

Japan's Ministry of Health, Labor and Welfare (MHLW) has implemented a positive list (PL) system for synthetic resins used in food-contact utensils, containers and packaging. The five-year transition period to complete "existing substances" evaluations ended on May 31, 2025, with broader updates expected to align simulants and testing. Suppliers should confirm resin listings and use conditions against the latest PL tables.

6 Other Global Trends to Watch

- *EU & Switzerland:* Continued alignment on plastics and recycled materials; Switzerland updated FCM annexes effective Jan. 1, 2025, tracking EU 10/2011.
- *Per- and polyfluoroalkyl substances (PFAS)/BPA & NIAS scrutiny:* Multiple jurisdictions are strengthening restrictions and documentation for Substances of Concern and NIAS, increasing analytical and toxicological burdens on suppliers.

7 Hygienic Design Standards Touching Mechanical Seals

While FDA, EU and GB rules regulate material safety, hygienic performance is guided by 3-A Sanitary Standards (U.S.) and EHEDG guidelines (EU). For seals, that typically means minimizing crevices, ensuring clean-in-place (CIP) access and validating cleanability—distinct from material safety authorizations and often overlooked in specifications.

8 Engineering Framework: Selecting Materials for Mechanical Seals

Use this five-step approach to select and document compliant seal materials across jurisdictions.

Step 1:

Define the regulatory envelope

- *Markets of sale and plant location:* U.S. (21 CFR/FCN), EU (1935/2004 + 2023/2006 + 10/2011 where applicable), China (GB 4806 series + GB 31603/31604), Japan (PL for resins), plus any national add-ons.

Step 2:

Map the intended use

- Food types (aqueous, acidic, alcoholic, fatty), contact class (direct/indirect), temperature/time, cleaning/sanitizers and frequency of CIP/sterilization-in-place (SIP). U.S. rubber extraction limits differ nine-fold for aqueous vs. fatty foods—critical for elastomer selection.

Step 3:

Choose candidate materials

- *Elastomers:* Ethylene propylene diene monomer (EPDM) for aqueous/acidic; fluoroelastomer (FKM) for oils/fats; nitrile butadiene rubber (NBR) or hydrogenated nitrile butadiene rubber

(HNBR) for moderate oils; silicone for wide temperature swing (verify oil/fat exposure); polytetrafluoroethylene (PTFE) or perfluoroelastomers (FFKM) for aggressive chemicals—always tied to jurisdictional lists and migration limits (EU 10/2011, GB 4806.x, Japan PL where resinous components are involved).

- *Metals:*
  Stainless steels (e.g., 316L) per GB 4806.9-2023 alloy-element migration and EU inertness principles; surface finish consistent with hygienic design.

Step 4:

Verify compliance and test plans

- *Documentation:*
  U.S. CFR citations or FCNs; EU DoC referencing 1935/2004, 2023/2006 and 10/2011 (if plastic), plus test reports; China DoC/labels per GB 4806.1; Japan PL confirmations for resin components.
- *Migration/extraction:*
  Conduct migration per food simulants and use conditions (EU 10/2011; GB 31604 series). For U.S. elastomers, ensure 177.2600 extraction compliance for the correct food type.

Step 5:

Hygienic design and life cycle controls

- Align seal geometry with 3-A/EHEDG cleanability expectations; specify surface roughness and crevice-free interfaces; document GMP/change control (EU 2023/2006, GB 31603) and maintain traceability/DoC updates.

9 Practical Materials Shortlist

Always validate against your specific food, jurisdiction and testing.

- *Aqueous/acidic foods, hot CIP:*
  EPDM or PTFE faces; 316L hardware; DoC under EU 1935/2004/2023/2006 (+10/2011 if applicable); GB 4806.9 metals compliance; U.S. 177.2600 extraction for EPDM.
- *High-fat foods, pasteurization:*
  FKM or FFKM elastomers; PTFE secondary components; ensure U.S. Hexane extraction limits, EU SMLs for any additive, GB additive lists under GB 9685.
- *Wide temperature swing, indirect contact:*
  Silicone (check oil/fat exposure and, for China, upcoming GB 4806.16-2025); verify PAA "ND" where adhesives are present.

10 Documentation Package Checklist for Procurement

1. Regulatory mapping (U.S./EU/China/Japan) with precise references (e.g., 21 CFR 177.2600, EU 1935/2004 + 2023/2006 + 10/2011, GB 4806.x + 31603/31604, Japan PL)
2. DoC (EU/China), including traceability and substance identity/purity/NIAS approach (per 10/2011 updates)
3. Migration/extraction test reports for relevant simulants and time/temperature (EU 10/2011; GB 31604; U.S. 177.2600 for elastomers)
4. GMP evidence (EU 2023/2006; China GB 31603)
5. Hygienic design rationale (3-A/EHEDG) and cleaning validation plan

Mechanical seals are a regulatory crossroads: material safety, hygienic design and real-world operating conditions converge. To avoid costly noncompliance, engineers should specify by jurisdiction and use condition, require fit-for-purpose extraction/migration testing and demand DoCs and GMP proof. A global mindset—spanning FDA's use-specific authorizations, the EU's framework and plastics measures, China's GB 4806 ecosystem and Japan's positive list—ensures seals are safe, auditable and durable across markets.

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For links to the above references, visit pumpsandsystems.com/indirect-food-contact-mechanical-seals. ■

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