TECHNICAL PAPER

FDA compliances — what do I need to know?

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Food and beverage producers rely on a wide range of equipment to ensure their products are safe and free of contamination. Sealing devices such as gaskets are key components in this equipment, yet do not receive the attention they warrant given the critical importance of their function.

Today's food manufacturing processes require the efficient handling of a wide range of process fluids, under varying conditions of temperature and pressure. Process lines and vessels must be resistant to a variety of fluids, ranging from basic chemical storage and handling through to manufacturing and waste management. Many of these process fluids are toxic and corrosive, and during sterilisation, temperatures can reach up to 160°C.

The fluid-handling system plays a critical role, yet experience has shown that the weakest link in manufacturing processes is often the sealing system – and specifically, seals used in couplings, flanges and other connection points in piping and equipment. Degradation of these seals can result in contamination of the final or intermediate products during manufacture and/or leakage, which may require a process shutdown, with subsequent product recalls involving significant financial and reputational costs.

To ensure sealing components can meet the unique challenges of industrial processes in food and beverage production, key compliances and standards are in place for materials used in these environments. The FDA is one of the most prominent bodies involved in this codification of safety standards. What is the FDA, what does their work involve, and how does it impact operators in food and pharmaceutical process industries?

Figure 1 — The Food and Drug Administration (FDA) logo

What is the FDA?

The Food and Drug Administration (FDA) is the US Federal Agency responsible for ensuring that foods are safe, wholesome and sanitary. The FDA also has a responsibility for the safety and efficacy of human and veterinary drugs, as well as a series of biological products, medical devices, cosmetics, and electronic products which emit radiation. Although the jurisdiction of the FDA is restricted to the United States, FDA regulations are adopted as international control standards. Through Codes of Federal Regulations the FDA promulgates a list of materials and chemicals that conform to the requirements for contact with foodstuffs.

At this point it should be noted that the FDA does not *approve* products to CFR 21.177.2600. It is for the manufacturer of the finished rubber product to demonstrate compliance by issuing a declaration of conformity. It is also important to note that whilst a component may be made from an FDA rubber material suitable for food contact, this does not mean that the finished part will automatically be suitable for its intended application. There are many other considerations (like temperature and chemical compatibility) to be made alongside the presence of an FDA certificate. It is advisable to consult individual material datasheets for full details of application suitability.

Challenges to seals in food process environments

The specific equipment and system conditions to be faced by a sealing material must be factored into the selection of a particular material type or grade. Many processing operations use steam to cook, but steam can also be used to sterilise, in a process commonly referred to as Steam-in-Place (SIP). In these cleaning applications, steam temperatures can be as high as 177°C, well above the temperature range of some materials commonly used in sealing products. Typically for heat sterilisation, use of products containing polymers such as acrylonitrile polymer (nitrile rubber) above 121°C could result in either polymer degradation or unwanted chemicals in the final product.

Thermal degradation from elevated processing temperatures or SIP operations could also negatively impact the organoleptic properties (taste and smell) of the product, or toxic byproducts that could migrate into the food process stream.

Alongside Steam-in-Place processes, there is another common cleaning method used in food and beverage processing facilities called Clean-in-Place (CIP). In CIP processes, chemical solutions are flushed through the equipment to remove residual process media and destroy any harmful bacteria or other microbial growth. These CIP solutions are typically caustic or acidic. Depending on the particular chemicals used, some elastomer types and grades may be totally unsuitable for use due to their low chemical resistance. A perfluoroelastomer (FFKM) is universally chemical resistant, but there are lower cost alternatives which may work well in certain environments. A sealing specialist can help to specify the most suitable seal for any chemical environment.

The true cost of cost-cutting?

The annual sealing product spend for a typical food and beverage manufacturing plant is likely well below one percent of the operating cost. Yet even considering this, sealing products are one of the first areas targeted for potential cost savings. The lower cost of budget sealing materials can be attractive, but customers should take the time to carefully examine the claims of cheaper sealing products, as the potential impact on operations can be highly detrimental. A small saving from switching to an unproven product that claims to be FDA-compliant could result in product contamination, product loss due to pathogens or other microorganisms, production downtime to decontaminate and sterilise or, worst case scenario, a complete product recall.

It is not possible to totally eliminate risk in any industrial environment, but risks can be managed much more effectively by securing sealing materials with the lowest migration levels and not those which just pass the specification.

A closer look at FDA codes

To be able to state compliance to any food contact materials regulation, two separate aspects must be considered:

- **Compositional compliance**
  each individual substance present in a material can be selected only from the relevant positive lists of allowed ingredients, as determined by the different regulations. Positive lists may also contain specific restrictions in terms of quantity, purity, final use or any other relevant parameter needed to protect the consumer's health;

- **Compliance testing**
  the regulations prescribe as well to carry out migration testing in food simulants to determine the overall migration and, in some cases, the migration of specific chemicals of concern, establishing maximum allowed values for both.

Both the above restrictions are to be met, although often in the technical and marketing literature more emphasis is posed on the migration testing; it has to be stressed that meeting the migration limits is not enough to state compliance, since the compositional compliance is equally important and mandatory.

More specifically considering the FDA regulations, each individual substance used in an elastomeric material to be used in contact with food shall be covered by one of the following:

(a) A regulation listed in Title 21 Code of Federal Regulations, specifically 21CFR177.2600 for rubbers

(b) Meeting the criteria for GRAS status

(c) A prior sanction letter

(d) A Threshold of Regulation (TOR) exemption request

(e) An effective Food Contact Substance Notification (FCN)

Below a brief explanation of the different positive lists present in the FDA legislation is reported.

21CFR177.2600 describes the relevant regulations for 'Rubber articles intended for repeated use'. It lists the ingredients and any quantitative limits, that may be used in a rubber compounds for moulded products intended for repeated use in all stages of food manufacture, preparation and transportation.

GRAS notices report a list of substances that are classified as Generally Recognised As Safe (GRAS) and can therefore be used in elastomer formulations.

In addition to GRAS substances, 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.

The Threshold of Regulation (TOR) exemptions database lists exemptions that have been issued for substances used in food-contact articles. This list includes, among other details, the chemical name of the substance, the specific use for which the substance received an exemption and any appropriate limitations on the substance.

Finally, the Food Contact Notification (FCN) database lists effective premarket notifications for food contact substances that have been demonstrated to be safe for their intended use. The list includes the food contact substance, the manufacturer, the intended use, the limitations on the conditions of use, etc.. Unlike the other positive lists mentioned above, a food contact notification (FCN) is proprietary, thus only effective for the manufacturer or supplier identified in the notification itself.

When it comes to defining the compliance testing conditions and thresholds, CFR21.177.2600 provides the guidelines with regards to rubber articles. Different levels (or Paragraphs) are laid down depending on the final application, that is if the seal is to be used for dry, aqueous or fatty foods. Generally, for dry food contact applications, **Paragraph A-D** apply and the sealing material must be compositionally compliant. There is no migration

testing requirement. However, for aqueous and fatty foods, migration testing on the sealing material is prescribed in boiling water and n-hexane respectively. When selecting a material and to reduce any risks, it is important to understand if the material has been tested to correct FDA requirements and how well the material has passed the migration tests. To reduce risk, it is best to select the material with the lowest migration level that is backed up with manufacturer's FDA declaration.

Paragraph E (Aqueous foods)

In this migration test (*Table 1*), the sample is refluxed for seven hours and then two hours in boiling distilled water, and the material extracted at each stage is measured.

	Extracted Material (mg/in^2)	
	Water (7hrs)	Water (2hrs)
Specification	<20	<1

Table 1 — Results table for FDA 21CFR177.2600 Paragraph E test

Paragraph F (Fatty foods)

In this migration test (*Table 2*), the sample is refluxed in n-Hexane for seven hours and then for two hours in a fresh aliquot of n-Hexane.

	Extracted Material (mg/in^2)	
	n-Hexane (7hrs)	n-Hexane (7hrs)
Specification	<175	<4

Table 2 — Results table for FDA 21CFR177.2600 Paragraph F test

It is important to be aware that some elastomers have additional migration testing requirements:

FDA 21CFR177.2400 Section d

This is a requirement for perfluoroelastomer (FFKM) only. In this test (*Table 3*) the sample is refluxed separately in distilled water, 50% ethanol and n-Heptane for two hours.

Extracted Material (mg/dm^2)		
Water	50% Ethanol	n-Heptane
<1.1	<3.1	<3.1

Table 3 — Results table for FDA 21CFR177.2400 Section d test

FDA CFR180.22

FDA CFR180.22 is a requirement for nitrile materials only. This test determines the level of unreacted acrylonitrile monomer that could potentially migrate to food, with the maximum FDA limit being 3µg/inch^2.

Fluoride extractives (ion chromatography)

The sample is refluxed separately in boiling distilled water, 50% ethanol and n-hexane for two hours, and extracts are analysed using ion chromatography to quantify the concentration of fluoride ions..

Extracted Material (mg/dm^2)		
Water	50% Ethanol	n-Heptane
<1.1	<3.1	<3.1

Table 4 — Results table for FDA 21CFR177.2400 Total Fluoride test

Summary

Food and pharmaceutical manufacturing applications present some of the most demanding environments for elastomer sealing systems. Unlike other industries where chemical or temperature resistance is the key seal selection criteria, food and pharmaceutical applications frequently have similar challenges and several more besides. These might include the requirement to never use materials which risk imparting taste onto the product.

Elastomers used in process equipment, pumps, valves, pipe work, couplings, reaction vessels and bulk containers must be able to cope with a wide range of process media, potent active pharmaceutical ingredients (APIs) and aggressive cleaning and sterilising processes. In addition, seals must be compliant with a growing range of legislative manufacturing regulations and hygiene standards. The FDA is a core element of this regulation.

Precision Polymer Engineering (PPE) offers sealing solutions which are compliant with the requirements of the Food and Drug Administration (FDA), as well as other leading regulatory bodies including United States Pharmacopeia (USP – Class VI). In addition, all PPE sealing materials are free from Animal Derived Ingredients. Certification for compliance to the appropriate specification or regulation is a pre-requisite. The extra in-depth knowledge of elastomer materials, in conjunction with regulatory requirements, ensures that a specialist sealing engineer is able to advise customers on the appropriate material specification for any application (see *Table 5* below).

Procuring seals from a specialist in hygienic sealing for food applications can negate the risks to safety and operational reliability inherent from using ‘low cost’ seal vendors with problematic and often misleading claims to ‘FDA compliance.’

Material	Grade	Max Temperature (°C)	Acids	Alkalis	Fats/ Oils	Alcohol	Solvents	Amines	Steam	FDA CFR21.177.2600 A-F	USP Class VI
EPDM	E70Q	150	2	1	4	1	2	2	1	Yes	Yes
FKM	V70SW	200	1	2	1	1	4	4	1	Yes	Yes
FFKM	Perlast® G74S	260	1	1	1	1	1	1	1	Yes	Yes
NBR	N70F	121	4	2	1	2	3	4	4	Yes	Yes
Silicone	S71U	200	4	2	2	1	4	2	3	Yes	Yes

Table 5 — Material compatibility against common process media, with FDA and USP compliances

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