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Forgotten duties of the food and beverage industry

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Executive summary

Hygiene, laws, recommendations and product diversity are just a few of the many complex topics with which today's food and beverage industry must cope. In the plethora of requirements and specifications, ostensibly unimportant C-parts, such as seals, are only too gladly forgotten and their effects on the overall process neglected.

This article should simultaneously be thought provoking and a source of help. It addresses three core aspects of seal technology in the food and beverage industry: material resistance, legal regulations and hygienic design.

Today's food and beverage industry faces a number of challenges.

First and foremost, process conditions are clearly of importance in seal engineering. Those in the pharmaceutical, cosmetic, chemical, and food and beverage industries resemble one another in many aspects.

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The basic commonalities can be subdivided into three pillars, which are applied with different emphases depending on the sector. They are material resistance, the fulfillment of relevant regulations and the demands for hygienic design.

This article can only delve into material stability in a general way because of the multitude of applications and processes. In practice, process media and temperatures, along with many other factors, must be considered individually and in detail.

The ability to meet fundamental legal requirements is the market's barrier to entry. In practice, it creates the greatest difficulty when seals are involved. For this reason, this article is especially devoted to this aspect.

The issue of hygienic design can only be addressed here with a few standard components such as tube connection seals, radial shaft seals or (hygienic) U-sits as examples.

Material resistance: The basic requirement

In choosing a seal, it is of primary importance to match the suitability of the sealing material to the application from a chemical, physical and mechanical standpoint. For one thing, the sealing material must be resistant to the process media. At the same time, it must withstand the CIP cleaning conditions and sterilization with steam or other sterilization media, such as peracetic acid.

Other challenges facing the sealing material are the highly complex mixtures that are found in carbonated soft drinks and energy drinks, consisting of many different components. The effect of the main component still can be well assessed. But a number of different components can elicit completely unexpected interactions. For example, ostensibly "harmless" material can potentially produce dangerous effects, and the effects of aggressive media can cancel each other out.

Another effect is the migration tendency of the compounds that are absorbed by the seal during food and beverage production can migrate out of it as well. Products, flavorings or cleaning and sterilization media can diffuse into the elastomer matrix.

Familiar examples are moving from a lemon lime soda to cola to a root beer to an orange drink down the same line. Special sealing solutions must often be selected. If this matter is not taken into consideration, the carryover of the flavor into other batches can result.

Fluoroprene XP is one material group that has been optimized for the minimization of flavor transfer.

Elastomers' compositions and methods of manufacture determine how they react to external influences. Elastomers consist of various ingredients that only maintain their special characteristics in their totality and after a chemical reaction known as vulcanization.

Rubber is extraordinarily elastic and therefore offers enormous damping and recovery behavior, which makes it the top choice in sealing technology. The meshing of the crosslinks within the elastomers provides this visco-elastic behavior.

It allows elastomers to be deformed reversibly and without damage. The base materials of elastomers are primarily all synthetic polymers. The basic elastomers give the material its fundamental characteristics such as chemical and thermal resistance.

From a quantity standpoint, the fillers are the second most important component in an elastomer recipe. This group is divided into "actively" reinforcing fillers such as carbon black and "inactive" fillers such as silica and barium sulfate.

The development of a high performing material is particularly demanding when the desire for colored elastomers compels the use of light-colored mineral-based fillers. The characteristics of light-colored materials are often not comparable to those of black materials, as numerous Freudenberg benchmark studies demonstrate.

Sometimes there is no alternative due to stringent purity standards or special color specifications. Here one must resort to special active light-colored fillers, which leads to the choice of high performance materials such as Freudenberg's white EPDM 253815.

Softeners can also be added to elastomer compounds. These relatively small molecules can easily dissolve out of the elastomer matrix, depending on the constituent it is exposed to. Of course, this migration tendency is absolutely undesirable in an industry such as the food and beverage that is sensitive to the issue.

In the interests of the consumer, the lowest possible quantities of extractable material are required from a legal standpoint as this may not only affect the flavor but may compromise the media passing by the seal as well. As a result, softeners often are not used to comply with legal demand for low migration values. Materials suited to food and beverage applications are therefore comparatively "dry," meaning softener-free.

The use of dry elastomer compounds can have a negative effect on coefficients of friction when it comes to dynamic applications. There are a multitude of methods relying on surface changes to effectively reduce the friction of elastomers. This in turn can lead to a situation where the legal approvals of the basic material can no longer be confirmed.

Some processes merely change the surface of the material in the nano range and elicit no adverse effects. The RFN (reduced friction by nanotechnology by Freudenberg) treatment is an example of this.

Legal requirements for elastomer seals in the food and beverage industry

The fulfillment of industry-specific regulations is the most important issue for the food and beverage industry. When seals are used in the industry, one key aspect involves the legal requirements of the countries where the fabricated products are due to be sold. For a company with global operations, this makes it necessary to observe many local regulations.

The most important approvals for the food and beverage on the elastomer side come from the U.S. Besides approvals in accordance with the U.S. Food and Drug Administration, such as NSF 51 (National Sanitary Foundation–Food Equipment Materials), 3-A Sanitary Standards may have to be used as well.

FDA Federal Regulation 21 CFR 177.2600, "Rubber articles intended for repeated use," is especially important. This regulation represents the industry's best-known example of the globalization of a requirement on elastomers. The apex of this development is its acceptance by many smaller countries since they may not have their own specific rules and

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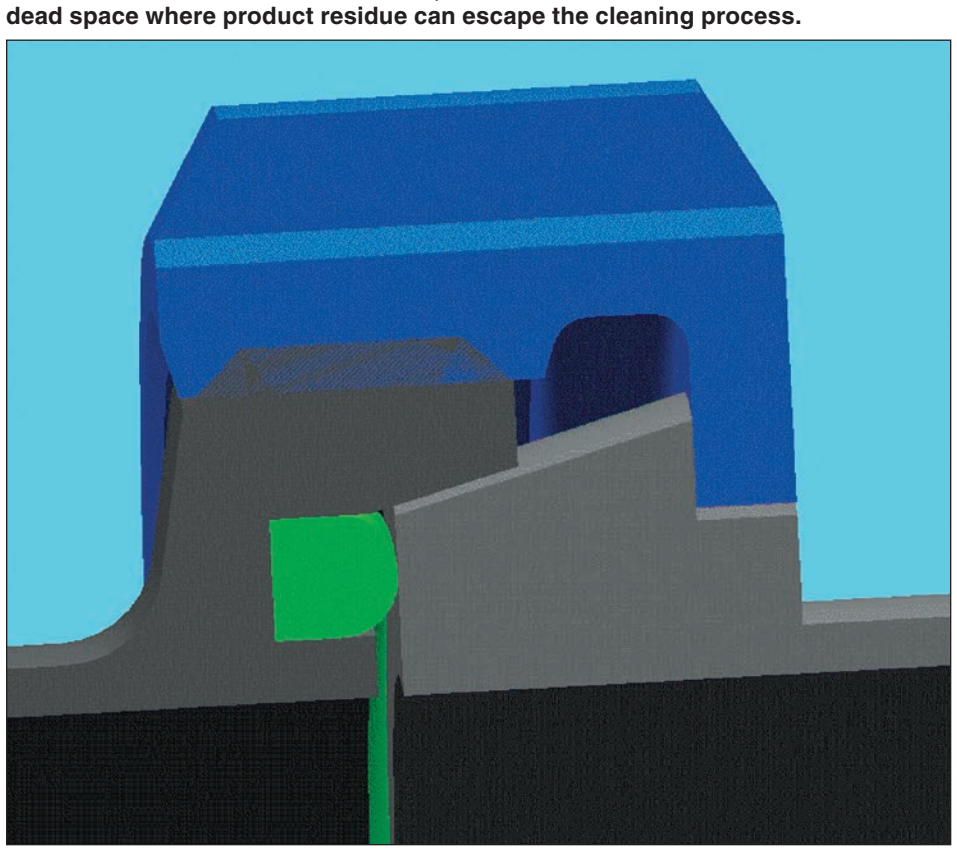
Fig. 1.1. "Milk tube fitting" in accordance with DIN 11851. The seal ("D-Ring") may be rotated in certain circumstances, but even with correct installation there is dead space where product residue can escape the cleaning process.



The authors

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Rory Pawl is director of sales, process industry, for Freudenberg-NOK Sealing Technologies.

He is responsible for sales and marketing for food and beverage, and pharmaceutical and chemical industries in North America. Freudenberg-NOK's process industry team specializes in addressing extreme temperature conditions, aggressive media, high hygienic standards and regulatory requirements.

Pawl has more than 17 years of experience in engineering, application development and management. He earned bachelor's and master's degrees in mechanical engineering from Lawrence Technological University and is a certified professional engineer in the State of Michigan.

After studying chemical engineering and doing his thesis at the Max-Planck-Institute for Polymer Research in Mainz, Germany, Christian Geubert started his career in the materials development department of Freudenberg Sealing Technologies. Later he took responsibility for elastomeric form parts and diaphragms in the process industry as a product manager for the Process Seals Division.

Geubert currently supports customers and sales engineers as an expert for sealing technology, apart from committee work at DIN, VDMA, ASME BPE and others.

He lectures on food technology at Cooperative State University Baden-Wuerttemberg and is the secretary of the German section of European Hygienic Engineering and Design Group.

He manages Freudenberg Sealing Technology's Application Engineering Process Industries global team with colleagues in Brazil and China.

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standards. In some cases, they have made a marginal change or created a supplement to the provisions. Even DIN standards require conformity with these clauses of U.S. law.

The manufacturer itself can declare FDA conformity under Paragraph 21 CFR 177.2600. If it has exclusively worked with the list of authorized substances—the so-called white list—during the development of the material, and it passes the two-stage extraction trials for aqueous foods in distilled water and for fatty foods in n-hexane, it is compliant.

Certification to FDA 21 CFR 177.2600 can be completed through NSF International or other third-party bodies. NSF 51 certification is achieved by submitting the ingredients that make up the elastomeric compound and comparing these to the allowed list of ingredients from the FDA. In some cases, the amount of certain ingredients is also reviewed. This third-party verification and certification becomes more and more often a requirement in the food equipment industry.

Testing under USP Class VI—or more aptly under USP Chapter 88 (in vivo)—actually is only required in the Pharmaceutical Industry, but it is also desirable in the food and beverage sector in some cases, such as for baby food.

An external test lab extracts the material with various media. An isotonic saline solution, the same with 5 percent ethanol as a solubility promoter, polyethylene glycol 400, and cottonseed oil serve as the test media. They all simulate various different tissue characteristics.

Fig. 1.2. "Clamp connection" in accordance with DIN 32676. Due to the lack of a guide and a metal block, there is the danger that the seal would be compressed unevenly and extruded into the product space.

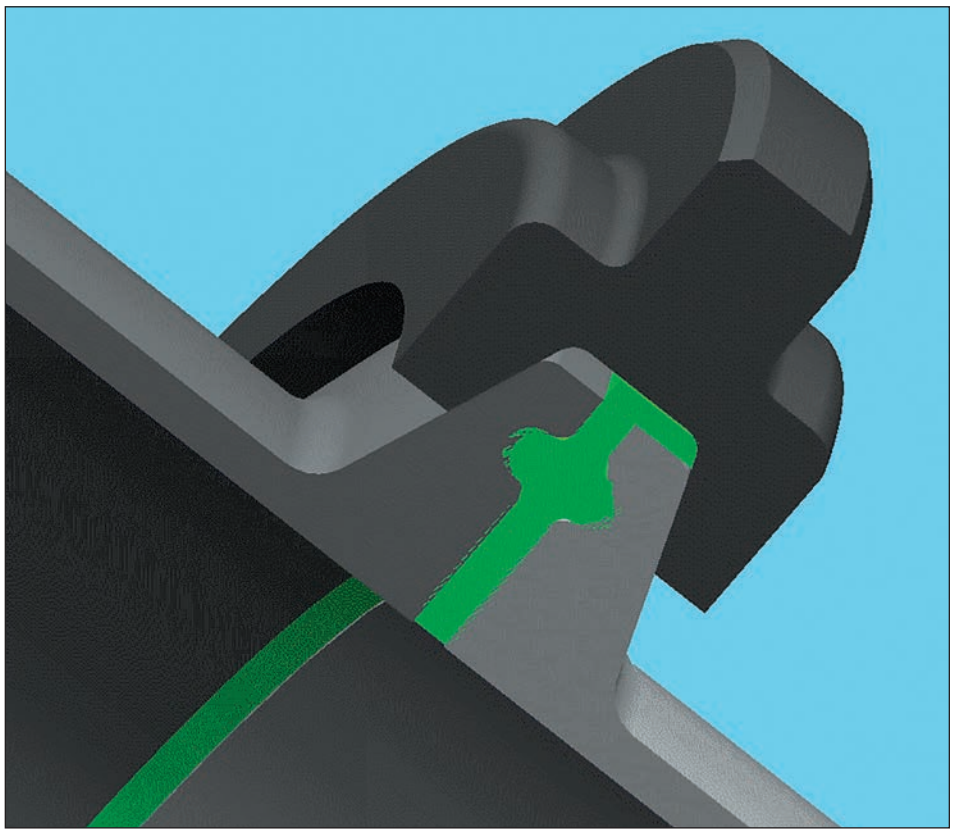
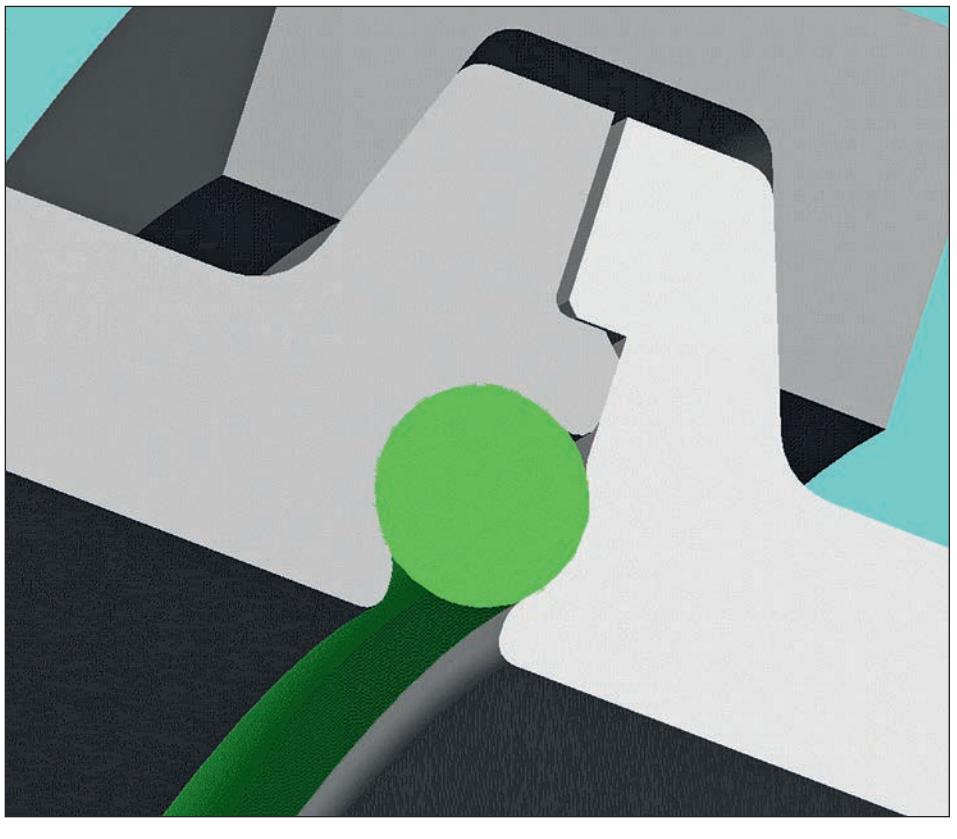


Fig. 1.3. Aseptic connection in accordance with DIN 11864. This connection fulfills the requirements of hygienic design for a guide, a block and a dead-space-free design.



The extracts, like the substance itself, are tested for their effect on living organisms. There is often testing under Chapter 87 (in vitro) before testing under USP Chapter 88. Due to different parameters, this cytotoxicity test is not directly comparable to testing in accordance with ISO 10993-5.

But it also examines the effect of elastomer ingredients on microorganisms. Here as well, not every material used in the food and beverage industry, for example, is suited for use, extractables studies show.

For the testing under 3-A Sanitary Standards, the material is tested in various process media found in the dairy industry and subjected to standardized cleaning processes. Based on the effect on the elastomer, a categorization by class is made. The 3-A standards historically come from the dairy industry, but also define the rules for hygienic design. Hygienic design makes it possible to produce safely and clean quickly.

The European Regulation (EC) 1935/2004 governs the requirements for materials that come into contact with food. In addition to the basic requirements of 1935/2004, individual material directives can be issued for the various groups of materials that come into contact with food (wood, glass, paper, plastics, elastomers, silicones, etc.)

Here it should be noted that individual measures need not exist for each material group. But the basic requirements of Regulation (EC) 1935/2004 must nonetheless be fulfilled.

Fig. 2. Dead-space-free radial shaft seal rings with forward-shifted lip.

The Regulation (EC) 2023/2006 is subordinated to the Regulation (EC) 1935/2004 and regulates individual measures promoting "good manufacturing practice" (GMP).

Article 3 of Regulation (EC) 1935/2004 requires that materials in contact with food must be produced in accordance with GMP. With the adoption of a term from the pharmaceutical industry for a requirement governing contact with foods, there is recognition that the two groups of requirements are approaching one another. Thus a validation of Regulation (EC) 1935/2004 is impossible without fulfilling the requirements of Regulation (EC) 2023/2006.

The Directive (EC) 2002/72 governed requirements for the use of plastics in contact with food until the end of 2015. This was a single directive in the spirit of Regulation (EC) 1935/2004. The directive did not apply to elastomers and silicones neither is a plastic material.

Each represents its own material group. To date, there have been no individual directives or even white lists for these groups. As a result, national law of European member states applies here. Among other things, the new regulation, in the form of Regulation (EC) 10/2011, contains a "white list" and migration tests. They must take later process parameters into consideration, making intensive communication along the supply chain necessary, especially for seals.

Since 2002, the German BfR (Federal Institute for Risk Assessment) has been assigned to make "recommendations on health assessments of plastics and other high polymers." These recommendations have no statutory standing but they represent the current state of scientific knowledge.

Elastomers are addressed in Recommendation XXI, which covers consumer goods based on natural and synthetic rubber, while silicone again is treated separately in Recommendation XV. Unfortunately, the BfR list and the FDA's white list are similar but not congruent. It is definitely possible for materials to meet the requirements of just one of the lists.

The requirements to fulfill all the relevant regulations and ensure material resistance put contradictory demands on seal materials. If a new material is developed, its selection as an ingredient is limited by legal provisions.

Only material on various white lists may be used. The materials should be designed to be as low-extract as possible, virtually inert even. The lifespan of the seal depends on the cleaning, sterilization and process media. Here it is essential to

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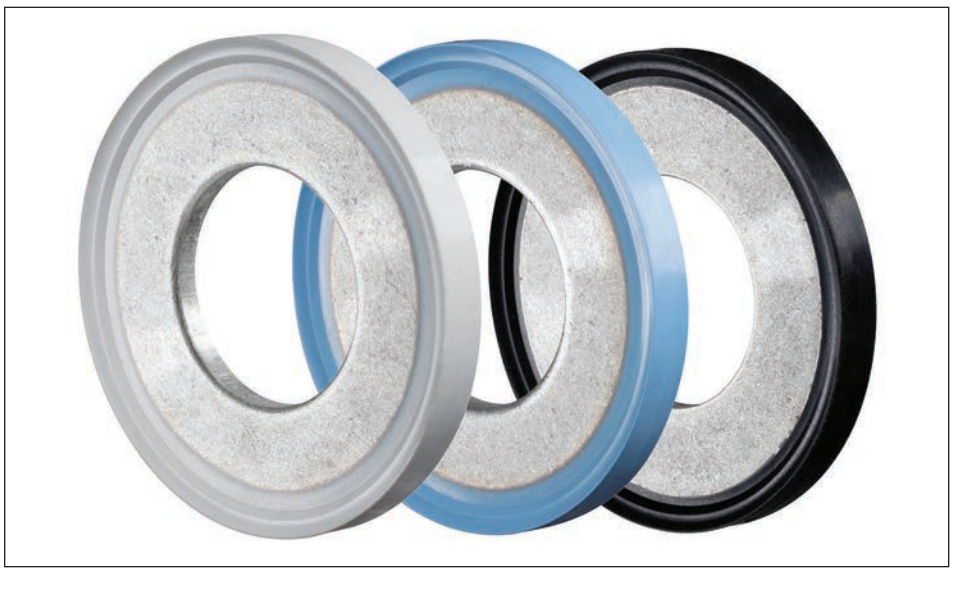
Fig. 3. The Hygienic U-sit, a metallic flat seal and elastomer seal in one component, provides FDA-compliant sealing screw connections, based on hygienic design.



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use seal material that has been especially developed for the application.

Examples of hygienic design seals used in food and beverage

Because it avoids gaps and dead spaces, hygienic design facilitates the cleaning process. Based on special design characteristics, it ensures that seals are not mounted improperly, for example. Hygienically designed elements also ensure that production and cleaning residue as well as excessive moisture do not form a foundation for biofilms.

Three seals for tube fitting, in particular, are widely used in the process industry and should be examined more closely here. The DIN 11851-compliant milk tube fitting is especially well known. Here it must be emphasized that, based on the standard, it should not be used in the pharmaceutical industry and should be phased out for food and chemical facilities.

In practice, however, the transitions are fluid. This connection is sealed with D-shaped elastomer ring **(Fig. 1.1)**. The connection produces dead space where product residue escapes the cleaning process and pockets of contamination can form. Since the seal can accidentally be installed in a rotated position, product residue can even accumulate in the groove. The "clamp connection" is a much better connection in terms of hygienic design.

This connection represents the standard in much of the equipment in the process industry, which is why it is still frequently required even today for the retrofitting or rebuilding equipment. They have no metal guide or block, however. This can lead to uneven compression and, as a result, to the extrusion of the seal into the product space.

Depending on the characteristics of the product and the strength of the flow of fluid, it can lead to the shearing-off of seal parts **(Fig. 1.2)**. An aseptic connection in accordance with DIN 11864 avoids these deficiencies. Hygienic design's requirements for a guide and a block are executed here.

The version of the connection with a close-tolerance O-ring is common. The guide and the metallic block ensure that the seal is compressed as specified and is not extruded. Moreover, there is no dead space whatsoever because the O-ring completely fills the groove. Even a certain amount of material swelling into the product space is taken into account in the design **(Fig. 1.3)**.

If a standard radial shaft seal ring is compared with the Radiamatic HTS II, which was especially developed for the process industry, their differences with regard to hygienic design become especially clear **(Fig. 3)**.

The standard design of a shaft seal ring with dust lip and spring contains dead space. Thus, residue-free cleaning is impossible. On the other hand, the forward-shifted seal lip of the Radiamatic HTS II closes flush, making it easy to clean. The product only comes into contact with the PTFE seal body, allowing no residue to accumulate.

Screw connections are found in nearly every component. That makes them very important when it comes to hygienic design. Metallic connections are still in use in the process industry. There is always dead space between metal and metal, and production residue as well as cleaning and sterilization media can accumulate there.

At the same time, an uncleanable source of contamination can form. Such standard screw connections, especially in direct contact with media, represent an unhygienic approach. Even in the open area subject to external cleaning, the connection can produce damage by promoting corrosion. The reason is that liquids collect under the screw head **(Fig. 4)**.

With the use of Hygienic U-sit, this risk can be avoided. Its elastomer seal lip, made of certified materials, permits the complete cleaning of screw connections. That is why they are suited to direct product contact.

At the same time, the screw or nut is mechanically tightened until it locks in place to assure a defined compression. In the process, it is essential to view the Hygienic U-sit as part of an overall concept. This requires the selection of a suitable screw and cover nut with flange in accordance with DIN EN 1665.

The above examples only represent a small selection of hygienic designs in the most diverse applications. Especially in sealing technology for the process industry, special customer-specific solutions are now the rule. But because of confidentiality agreements, they cannot be presented here.

Summary and Outlook

In the process industry, seals are often viewed as low-value components. That is why the minimum amount of time and money is expended on them. In view of their function in the overall process and their relevance to hygiene, however, they are of great importance. Seal-specific regulations and requirements are thus among the often forgotten duties of equipment manufacturers and operators in the process industry.

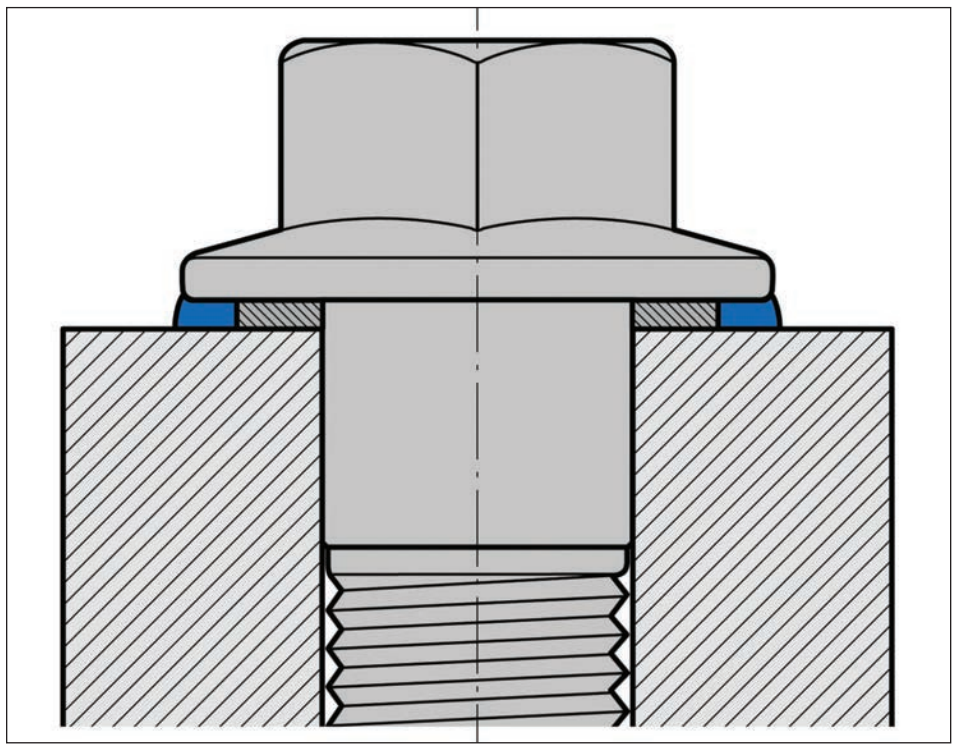
Export-oriented companies should take into account the local provisions abroad or choose a seal specialist that is totally familiar with the process industry's market.

Aside from the fulfillment of the relevant legal fundamentals and hygienic design, a knowledge of chemical resistance requires close cooperation with seal specialists. The demands on seals will continue to increase in the future as growing product diversity and the development of new ingredients require continual compatibility testing.

Efficient and flexible production facilities require seals that have longer operating lives and simultaneously offer maximum purity.

For more information, please visit: https://www.fst.com/markets/process-industry.

Fig. 4. Hygienic screw connection, right side U-sit flyer



News Digest

Acquisitions help Freudenberg in 2016

DETROIT—Despite what it called challenging conditions across multiple market segments, the Freudenberg Group posted profitable growth in 2016 thanks to several key acquisitions.

Taken together, the purchases of Vibracoustic Group and Japan Vilene Co. had the largest positive impact on sales, boosting Freudenberg's revenue by $1.07 billion. Factoring the exchange rate and acquisition effects, Freudenberg said organic growth amounted to 3.7 percent last year.

In North America, Freudenberg's 11 business groups reported $2.5 billion in sales, an improvement of 15 percent compared to the previous year. These increases, according to Bob Evans, Freudenberg North America president and regional representative, are the result of investments made by the firm throughout the year.

Freudenberg's Chem-Trend business will invest in its global headquarters in Howell, Mich. The project will expand existing research and development facilities by about 50 percent and will allow for continued growth of its R&D activities.

A. Schulman remains optimistic

FAIRLAWN, Ohio—Materials maker A. Schulman Inc. posted lower results in the first half of its 2017 fiscal year, but officials remain optimistic about the firm's performance.

Schulman's sales dropped about 6 percent to $1.2 billion in the six months ended Feb. 28. Profit for that period slipped more than 10 percent to $8.5 million.

Sales grew almost 10 percent in Asia-Pacific, but fell 7 percent in EMEA, almost 12 percent in U.S./Canada and almost 2 percent in Latin America.

Based on products, the firm's Engineered Composites sales grew 6.5 percent for the half, but sales of Custom Concentrates and Services slid 5 percent and Performance Materials slipped almost 9 percent.

AmSty operation resumes production

ST. JAMES, La.—Americas Styrenics L.L.C. has resumed full production of styrene monomer at its plant in St. James.

Production of styrene, a polystyrene feedstock, had been down at the site in recent months because of repairs that were needed on critical equipment.

Officials with AmSty in The Woodlands, Texas, previously had said that the firm's PS resin production hadn't been affected by the styrene outage.

RMA honors four with safety awards

WASHINGTON—Four U.S. tire manufacturers have won Safety and Health Improvement awards from the Rubber Manufacturers Association for excellence and improvements in worker health and safety.

Michelin North America Inc. was the big winner this year, receiving four Excellence awards for its plants at Columbia, S.C.; Greenville, S.C.; Midland City, Ala.; and Starr, S.C.

The Excellence category is for tire facilities that have achieved a Days Away Restricted Transfer rate 75 or more percent better than the average achieved by all plants that provided data to the RMA.

Twelve more facilities won Improvement awards, signifying that their DART rates are both 10 percent better than the previous year and the same or better than the RMA average incidence rate, the RMA said.

The Improvement winners are:

- Bridgestone Americas Inc.: Bloomington, Ill.; Long Beach, Calif.; Warren County, Tenn.; and Wilson, N.C.
- Cooper Tire & Rubber Co.: Tupelo, Miss.
- Goodyear Tire & Rubber Co.: Lawton, Okla., and Akron.

MidAtlantic group to host meeting

WEST CONSHOHOKEN, Pa.—The MidAtlantic Rubber & Plastic Group will host its Spring Technical Meeting May 11 at the ASTM International World Headquarters in West Conshohoken, Pa.

The program "Collaborative Testing of Rubber, Plastic & Their Blends" includes a presentation by Alyson Fick, ASTM manager of international technical committee operations. She will kick off the event at 2:30 p.m. with an overview of ASTM.

IISRP to hold webinar May 10

HOUSTON—The IISRP will host a one-hour webinar May 10, giving participants the opportunity to learn more about some of the more recent trends, applications and developments within the elastomer and synthetic rubber industry.

Walter Ramirez, chief innovation officer and founder of technology-market innovation firm Innentik S.L., will lead the webinar. His presentation titled, "Recent Developments and Applications in Elastomers and Synthetic Rubber."

Additional information about the webinar, including online registration, is available at www.iisrp.com, under the webinar tab. The cost for the program is $50 for IISRP member companies and $200 for non-members. Space is limited to 100 participants.