

**Impact of the current draft of the PFAS proposal
on connections and seals
for food, beverage, chemical and pharmaceutical applications
DIN NAA**

Dear ECHA Committee Members:

DIN NAA is a committee within the German standards organization, which is publishing consensus standards related to tubes, flanges and connections used for food, beverage, chemical and pharmaceutical applications. The tubes, elbows, tee pieces and connections are, together with hoses and sensor equipment, used in the process industry worldwide.

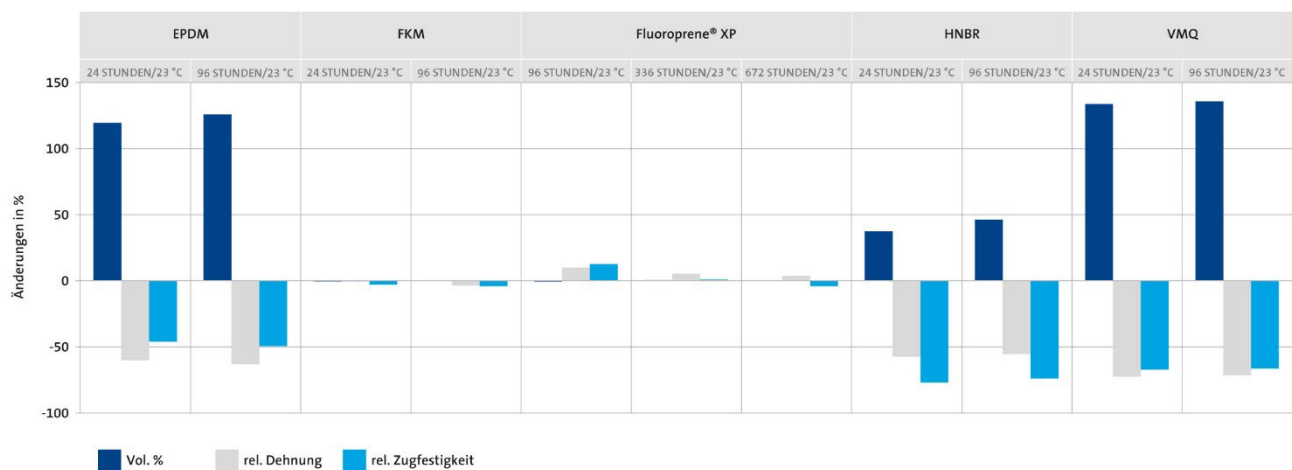
Members of the DIN NAA committee represent the entire supply chain from material manufacturers, seals and component, assembly and equipment manufacturers to equipment owner and users themselves. DIN NAA is in permanent contact with other organizations related to the process industry like CEN, ASME BPE and EHEDG to exchange about state-of-the-art best practices and solutions, thus standards are meeting the latest developments of this delicate industry.

We would like to take the opportunity to comment on the current proposal of the PFAS regulation for the European Union and share our views how it will affect the global process industry from our current joint understanding.

Sealing products made from elastomers and PTFE are a vital part of above said connections and essential for the connection's or the overall equipment's functions.

Sealing products made from fluorinated polymers (FKM, FFKM, FEP, PTFE) are used where process conditions are harsh and chemically and thermally challenging. The alternatives available and being present in the standards – EPDM, NBR, HNBR and VMQ – do not possess the same properties the fluorinated materials offer, nor are there any suitable alternatives to these already mentioned known to the committee.

In particular cleaning and sterilizing cycles involving higher amounts of acid used in food, beverage and pharmaceutical production often deteriorate seals made from NBR and HNBR, sterilizing steps involving steam above 120°C break up the Si-O-bonds of the VMQ and destroy the material on the long term. EPDM itself cannot be used, when fatty or oily products are present, as seals made from EPDM will swell and increase their volume detrimentally. The swollen or deteriorated seal can then be torn of, with the result of seal particles as foreign matter being present in products and creating an avoidable risk to the consumer. To tackle this challenge sealing products' materials are chosen carefully by equipment users together with their equipment and sealing suppliers being consulted. In the beverage industry, 80% of the seals are made of EPDM, but the remaining 20% require much more expensive fluorinated materials due to the nature of the drinks. Flavors like the natural substance Limonene present in oranges are aggressive and lead to extensive swelling where only fluorinated materials are possible to use, see diagram 1:



The already mentioned much higher price of fluorinated materials (3 to 4 at FKM and up to 70 to 80 with FFKM) compared to the alternatives limits their usage to the absolute minimum needed by itself. Being forced to produce these foods and beverages and pharmaceutical products without fluorinated sealing materials may lead to excessive waste due to contamination, potential leakage of product endangers humans by creating workplace safety issues when maintenance cycles are not reduced to a quarter of the former lifetime (estimated figures, no data available), but also may have an adverse effect on the environment when leakage rates are by far higher than with fluorinated materials. Finally, some reactions within the pharmaceutical and chemical industry may not be possible, as pressure, temperature and time as the needed variables of the reaction are beyond reach.

The OECD has defined polymers as a material class of low concern (insignificant environmental and human health impacts.). Additionally, the fluorinated materials in question have been tested excessively in the different applications for food, beverage, chemical and pharmaceutical applications. Depending on the customer's application some of the materials underwent even pharmaceutical compliance testing according to United States Pharmacopeia (USP) chapter 87 or ISO 10993-5 (in vitro) and/or USP chapter 88 or ISO 10993-6, -10 and -11 (in vivo). Further testing is done according to food contact legislations around the world, depending on the application. In order for not endangering human health, this excessive regime of testing is required by law and proves the stability of these materials.

With the prerequisites and provisions mentioned above about the usage of sealing materials within the process industry, it is the strongest belief of this committee, that forbidding the usage of fluorinated materials for sealing applications is not the best way forward to a sustainable and safe future.

Therefore DIN NAA recommends to exempt polymeric, long-chain materials used for sealing applications within the process industry from the current PFAS legislation. We kindly ask that you take these considerations specific to the process industry into account before any final decisions that all fluoropolymers and fluoroelastomers receive any kind of restriction from your committee are made.