Position Paper on the Potential Ban of PFAS on Food Contact Surfaces in Food Manufacturing/Processing Equipment by the European Hygienic Engineering & Design Group (EHEDG)

Date: 16 August, 2023

Content:

Introduction of EHEDG

The European Hygienic Engineering and Design Group (EHEDG) foundation is a non-profit organisation that provides practical guidance on hygienic engineering for manufacturing safe and wholesome food. Founded in 1989, we have been connecting food producers, food processing companies, equipment manufacturers, universities, research institutes and public health authorities with the aim of supporting and shaping the future of food safety and quality. It is our common aim is to promote hygiene during the processing and packaging of food products. From a handful of European-based organisations like Unilever and GEA Group, we are now proudly counting, the participation of expert volunteers, from over 750 contributing organisations and individuals, in over 40 countries, in all continents.

From the first guidelines for pipe couplings and valves, we are today maintaining an inventory of over nearly 60 industry guideline documents addressing 10 focus areas, to better serve the food and hygienic design market in a time of rapid industrial and technological changes. From traditional lectures, we can today provide educational offerings and networking opportunities with different modes of delivery.
From a simple certification programme, we now offer a sophisticated scheme, comprising of different equipment types and classes, supported by 12 Authorised Evaluation Officers and 8 Authorised Testing Laboratories.

Vision & Mission
The aspirational goal that drives the European Hygienic Engineering and Design Group (EHEDG) foundation is to be the leading source of hygienic design and engineering expertise, to improve food safety and quality across the food production and food processing industry.

EHEDG is committed to raise awareness of hygienic design and engineering among the various target groups, to develop guidelines and solutions, to provide a platform to promote our expertise and facilitate networking across the world.

Objective
The aim of the EHEDG foundation is to form a balanced forum of, and for, suppliers of food production equipment and installations for the processing of raw materials, the production of semi-finished products and final foods / ingredients, the end users (the food processing industry), and legislators. This forum is to encourage discussion of all aspects of hygienic design and related processes and procedures, to bring food safety and food quality to the next level.

This is achieved, among others, through:
a) establishing and publishing guidelines for the hygienic design of equipment, installations and buildings, based on daily practical experience and scientific findings;
b) developing test methods so that devices comply with the EHEDG guidelines; monitoring the implementation of the tests by the test institutes;
c) maintaining a certification scheme for equipment used in the food industry;
d) promoting worldwide harmonization of the hygienic design guidelines and related processes with all kinds of organisations active in the food industry and food safety management such as 3-A SSI, GFSI, BRCGS, FSSC, IFS, Cen, and ISO;
e) disseminating knowledge by organizing conferences, study days and workshops and offering a virtual knowledge platform;
f) identifying sub-areas where we lack information, and promote research in these areas;
g) safeguarding the content value of EHEDG, including proper use of the trademark and logos;
h) forming a point of contact in the broadest sense of the word, which is related to our objective.

REACH Regulations on the use of PFAS

The EHEDG acknowledges the importance of addressing environmental and health concerns related to per- and polyfluoroalkyl substances (PFAS) under the REACH regulation. The EHEDG organisation is dedicated to promoting hygienic engineering and design practices, we understand the need to balance sustainability, safety, and innovation in the manufacturing sector.

We acknowledge the concerns surrounding the high persistence, mobility, bioaccumulation potential, long-distance transport potential, global warming potential, and ecotoxicity of certain PFAS substances.

EHEDG therefore fully supports the goal of preventing PFAS classified as very dangerous from entering the environment. However, we believe that a more differentiated and risk-based approach is necessary to address the potential ban of PFAS in materials used in (food) equipment and plant engineering. The current restriction proposal requires further refinement to ensure both environmental protection and the continuity of essential (food) industry processes.

For food production the Annex XV Restriction Report states:

“ … 6a) For food contact materials used in the industrial production of food and feed, a time limited derogation is proposed. The following applications are inter alia covered by this derogation:

• Piping and tubing for drinking water applications;

EHEDG Office
Karspeldreef 8
1101 CJ Amsterdam-Zuidoost

E-Mail [redacted]@ehedg.org
Internet www.ehedg.org

Stichting EHEDG (Registered Seat)
Reg.-No.: 24290385

President: Hein Timmerman
Operations Director: Adwy van den Berg

• Filters to capture contaminants from, for example, steam filtration in food processing;

• Seals, O-rings, gaskets, tubing and pipes, expansion joints;

• Valves and fitments, conveyor belting, chutes, guiding rails, rollers, funnels and sliding plates, tanks, funnels, rollers, linings, blades of knives and scissors, springs, filter membranes and sensor covers, lubricants;

Packaging of food and feed products, non-stick coatings in the industrial and professional food and feed production (e.g. industrial cookware, covered under paragraph 6g) as well as food contact materials for use in consumer articles shall not be covered by this derogation. …"

" … 6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF; …"

" … The following potential derogations are marked for reconsideration after the Annex XV report consultation: g. [non-stick coatings in industrial and professional bakeware until 6.5 years after EiF]; … "

This enhanced position paper outlines the EHEDG evaluation of the restriction proposal and presents recommendations for a balanced and sustainable solution.

Evaluation of the Restriction Proposal

- Scientific Risk Assessment

The chemical scope of the restriction proposal is broad, encompassing F-gases, low-molecular compounds, and fluoropolymers, totalling around 10,000 different PFAS. We acknowledge the challenge of individually regulating each substance and propose a risk-based approach to differentiate PFAS based on their hazardous properties.

When evaluating the restriction proposal, the route of entry into the environment for different PFAS subgroups must be taken into account. Applications like fluoropolymer seals used in enclosed spaces within machinery pose minimal risk to the environment and should be considered for exceptions. After usage when the seal is being replaced the old seal will be disposed and incinerated, the polymer will be decomposed and will not get into the environment. The subsequent molecules, after incineration, show no risk.

- Toxicity

Fluoroplastics like PTFE and rubbers (FKM, FFKM, FVMQ) are often used in the food and beverage industry for demanding applications with high temperatures and aggressive media. These materials consist of large, long-chain molecules and belong to the group of polymeric PFAS and are classified as "polymers of low concern" according to OECD criteria. This means that fluoropolymers and products that contain fluoropolymers pose no risk to human health and the environment when they are used properly. [See Appendix 3: sources 1), 2) and 3)]

In medical applications for example these materials must meet additional requirements with regard to their toxicological safety. Their non-toxic behaviour has been demonstrated by fulfilling tests in accordance with the USP guidelines USP Chapter 87 Biological Reactivity Tests, in vitro & USP Chapter

88 Biological Reactivity Tests, in vivo. The tests are designed to determine the biological reactivity of mammalian cell cultures after contact with elastomeric and other polymeric materials with direct or indirect patient contact or with specific extracts prepared from the materials to be tested as well as the biological response of animals to elastomers, plastics and other polymeric materials through direct contact or by injection of specific extracts prepared from the material to be tested.

- Differentiation of Industrial Applications

It is crucial to differentiate industrial applications from consumer goods. Fluoropolymers, such as PTFE, ETFE, FEP, PFA, PVDF, and VDF-co-HFP, have been scientifically evaluated as "polymers of low concern" due to their stability, non-toxicity, non-bioavailability, non-water solubility, and non-mobility. Making them suitable for applications like food contact and medical technology. Therefore, EHEDG proposes exempting fluoropolymers from the PFAS restriction, and any substances required for their safe use should also be exempted. Similarly, applications with no relevant risk to the environment, such as enclosed fluoropolymer seals in machines, should be considered for exceptions. Provided that monomers and processing aids required for their manufacture and production are ensured to be safe.

- Substitutability and Availability of Alternatives

For industrial applications facing extreme conditions, such as high temperatures, high pressure, UV radiation, high frictional resistance, or exposure to aggressive chemicals, suitable alternatives to PFAS-containing materials are scarce. Actually, no suitable alternatives exist for some of these uses as we speak and development of suitable alternatives will probably take decades. Meaning that the 6.5 year grace period will probably not be sufficient for the industry to develop commonly usable safe alternatives. This timeline is based on the process that includes development of alternative materials and testing by the supplier, integration and testing by the equipment manufacturers, testing, validation and acceptance of the food producing and processing industry.

To facilitate the process and prevent unforeseen disruptions, EHEDG advocates for an uncomplicated and unbureaucratic application for the extension of exceptions beyond the initial period. This approach ensures that viable alternatives have adequate time for evaluation and implementation. EHEDG urges a thorough examination of available alternatives, considering technical maturity, safety aspects, energy consumption, and service life. Until viable replacements are identified, certain industrial applications should be exempted from the PFAS ban to maintain safety and efficiency.

The high price of PFAS ensures their limited use, indicating that they are employed only when necessary. It is essential to thoroughly evaluate the availability of equivalent alternatives before imposing a complete ban, as these unique materials contribute to the safety, resource efficiency, and longevity of industrial plants

- Spare and Used Parts

To promote sustainability and cost-effectiveness, EHEDG requests exceptions to the restriction should be granted for placing spare, wear, and used parts on the market. This principle of repair as produced should be valid for an indefinite or considerably longer period than currently planned transitional periods.

- Toxicity Risks

The disposal of fluoropolymers under the conditions common in European waste incineration plants does not produce PFAS of concern:

The results confirm that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. [See Appendix 3; source 4)]

When fluoropolymers are incinerated, the resulting fluorine compounds are decomposed and the evolving hydrogen fluoride gas is separated in gas scrubbers; no PFAS are released into the environment. [See Appendix 3; source 5)]

These have carbon polymer backbone with the fluorine atoms attached directly to the carbon backbone. These polymers do not lead to the formation of long-chain PFAS or PFAC as a result of degradation." [See Appendix 3; source 6)]

A comprehensive scientific risk assessment should be conducted to identify restricted substances within specific groups with comparable hazardous characteristics. This approach will allow the continuation of uses that do not pose a significant risk to human health or the environment, in the different purposes these materials are used for as seals and packaging materials in the food industry.

- Transparency and Avoidance of Double Regulation

EHEDG highlights the need for ensuring consistency and coherence between the universal PFAS regulation and other relevant EU regulations, such as the F-Gas Regulation. A transparent list of affected substances, including IUPAC names, CAS numbers, and EU numbers, must be communicated to allow companies to collect information along the international supply chain. Additionally, coherence with other EU regulations, particularly the (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases, (EC) No 1935/2004 on materials and articles intended to come into contact with food, (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, must be ensured to avoid double regulation, minimize confusion and enhance regulatory effectiveness.

Conclusion

EHEDG acknowledges the need to address the environmental risks associated with PFAS, but we emphasize the importance of a balanced and risk-based approach. While we support the goal of restricting PFAS classified as very dangerous, it is essential to differentiate industrial applications from consumer goods and to ensure the availability of suitable alternatives. The mechanical and plant engineering sector plays a critical role in various industries, and the potential ban of PFAS must be carefully evaluated to prevent devastating consequences for the European economy. We urge the European Chemicals Agency (ECHA) and the relevant authorities to consider our recommendations and work collaboratively with industry stakeholders to develop a sustainable and effective solution.

Appendix 1 - Definitions

In which parts, equipment, machinery and food producing and processing applications used as Food Contact Materials (FCM) is PFAS being used? Below some examples are given, this is not an exhaustive list.

Baking plates/pans
A baking plate in hygienic design for food processing is a flat, heat-resistant surface, usually made of food-grade materials such as stainless steel, aluminium or carbon steel or, used for baking and cooking food products. Baking plates are designed with smooth, easily cleanable surfaces to maintain high levels of hygiene, prevent cross-contamination, and ensure safe food production in the food processing industry. Non-sticking coatings are applied depending on the FCM.

Bellows
A bellow in hygienic design for food processing refers to a flexible, accordion-like component made of food-grade materials, such as PTFE, used to cover joints or gaps in equipment and piping. Bellows are designed to prevent the accumulation of debris, moisture, and contaminants, ensuring easy cleaning and maintaining hygienic conditions in the processing environment. They help to minimize the risk of product contamination and improve the overall sanitation of food processing equipment and systems.

Blades
A blade refers to a cutting or mixing tool typically made of food-safe materials like stainless steel. Blades are used in various food processing equipment, such as mixers, cutters, and blenders, to process and prepare food products. Blades are designed with smooth surfaces, easy-to-clean edges, and hygienic construction to ensure food safety and prevent the build-up of contaminants. Non-sticking coatings are applied depending on the FCM.

Chutes
Chutes are inclined channels or surfaces that allow the controlled and hygienic transfer of food products from one processing stage to another. Chutes are designed with smooth, easy-to-clean surfaces, avoiding crevices or corners where food particles might accumulate. By maintaining cleanliness and minimizing the risk of contamination, chutes ensure the safe and efficient movement of food items within the processing facility, promoting high-quality and safe food production. Non-sticking coatings are applied depending on the FCM.

Coatings
Coatings refer to specialized surface treatments or layers applied to equipment and surfaces to ensure food safety, hygiene, and sanitation. Coatings are made of food-grade materials and are designed to create smooth, non-porous, and easy-to-clean surfaces that resist the adherence of contaminants, bacteria, and other impurities. By employing hygienic coatings, the risk of cross-contamination and product spoilage is minimized, promoting a clean and sanitary environment throughout the food processing facility.

Conveyor belts and systems
Conveyor belts and systems are mechanical equipment used to transport food products along a production line or processing facility. Conveyor belts and systems consist of belts made from food-safe materials, supported by hygienic structures, and designed with easy-to-clean surfaces to prevent the accumulation of debris, bacteria, or other contaminants. By maintaining strict hygiene standards,

conveyor belts and systems ensure the safe and efficient movement of food items during various stages of food processing, promoting food safety and quality.

Diaphragm
A diaphragm refers a thin sheet of material forming a non-porous partition between the product and a measuring sensor or an actuator. A flexible, often rubber-like membrane used in specialized equipment such as diaphragm pumps or valves. It acts as a barrier between the fluid being processed and the mechanical components, ensuring that the product remains isolated from the internal parts of the equipment. Diaphragms are designed to meet strict hygienic standards, allowing for easy cleaning and preventing contamination, making them suitable for handling sensitive food products while ensuring food safety and quality during processing. These diaphragms can contain FKM as well as PTFE materials.

Filters
Filters are components used to remove impurities, particles, or contaminants from fluids and gases during various stages of food production. These filters are designed with food-safe materials and smooth surfaces, ensuring they are easy to clean and maintain hygiene. By effectively removing unwanted substances, filters help to ensure the purity, safety, and quality of food products while meeting stringent sanitary standards in the processing environment. Fluoroplastics like PTFE and rubbers (FKM, FFKM, FVMQ) are often used as FCM.

Fitments
In the context of hygienic design for food processing, fitments refer to specialized components or attachments used in food processing equipment to facilitate proper assembly, connection, or sealing. Fitments are designed to meet strict hygienic standards, often made of food-grade materials, and have smooth, easily cleanable surfaces. They play a crucial role in maintaining the sanitary integrity of food processing equipment, ensuring efficient operations, and preventing contamination during the production process.

Funnels
Funnels are conical or tubular devices used to direct the flow of food products or ingredients into containers, machines, or processing equipment. Funnels are designed with smooth, easy-to-clean surfaces and made from food-safe materials, ensuring they meet strict hygiene standards. By facilitating efficient and contamination-free transfer of food items, funnels contribute to maintaining a clean and safe processing environment while promoting the quality and integrity of food products during production.

Gaskets
Gaskets are seals made of food-grade materials, typically rubber, silicone, or fluoroplastics like PTFE and rubbers (FKM, FFKM) used to prevent leakage and ensure airtight or watertight connections between various components and equipment in the food processing industry. These gaskets are designed with smooth surfaces and easy-to-clean properties to maintain hygiene and prevent contamination. By providing secure seals, gaskets play a critical role in maintaining food safety and sanitation standards while preserving the quality of food products during processing.

Guiding rails
Guiding rails are specialized tracks or channels made of food-grade materials, used to guide and direct the movement of food products or processing equipment along a production line. These rails are designed with smooth surfaces and easy-to-clean properties to prevent the accumulation of debris or contaminants. By ensuring precise and hygienic alignment of products and machinery,

guiding rails contribute to the efficient and safe movement of food items during various stages of food processing, promoting food safety and quality.

Heat exchangers
Heat exchangers are equipment used to transfer heat between two fluids while keeping them physically separated to ensure food safety and hygiene. They play a crucial role in heating or cooling food products during various processing stages, without direct contact between the food and the heating or cooling medium. Heat exchangers are designed with smooth, easy-to-clean surfaces and made from food-grade materials to prevent contamination and maintain strict hygiene standards, ensuring the quality and safety of food products throughout the processing operation. Elastomeric seals are applied in between the different materials to ensure leak-proof equipment.

Joints
Joints refer to the connections or unions between different components or sections of food processing equipment or piping systems. Joints are designed to meet stringent hygiene standards, often using food-safe materials and smooth surfaces that are easy to clean and prevent the accumulation of contaminants. Properly designed and maintained joints ensure leak-proof connections and help to maintain the overall sanitary integrity of food processing equipment, reducing the risk of contamination and ensuring food safety during the production process.

Knives
Knives are specialized cutting tools used to slice, chop, or trim food products during various stages of food production. These knives are designed with smooth, easy-to-clean surfaces and made from food-grade materials to meet strict hygiene standards. Ensuring the knives are properly cleaned and sanitized is crucial to prevent cross-contamination and maintain food safety. By providing precise and sanitary cutting, knives play a vital role in producing high-quality and safe food products in the processing industry.

Linings
Linings refer to protective layers or coatings applied to the interior surfaces of equipment, containers, or structures to maintain food safety and hygiene. These linings are made from food-grade materials and designed to have smooth, non-porous surfaces, ensuring easy cleaning and preventing the accumulation of contaminants. By providing a barrier between the food products and the equipment surfaces, linings help to prevent potential interactions that could compromise food quality or introduce health hazards. Properly applied and maintained linings are essential for maintaining a clean and sanitary environment during food processing, ensuring the production of safe and high-quality food products.

Lubricants
Lubricants are substances used to reduce friction and facilitate smooth movement between mechanical components and equipment used in the food industry. These lubricants are specially formulated with food-grade materials and are designed to meet strict hygiene standards. They are applied in a way that prevents contact with food products, ensuring that the lubricants do not contaminate the food during processing. Properly selected and used lubricants play a critical role in maintaining the efficiency and longevity of food processing equipment while ensuring food safety and adherence to sanitation regulations.

Membranes
An engineered porous material that is permeable to a liquid, gas, or air. For example, a reverse osmosis membrane for water treatment. (See Diaphragm, Barrier)

Membranes refer to thin, flexible barriers or filters made of food-safe materials, used to separate different substances or control the flow of fluids during food production. These membranes are designed to meet strict hygiene standards, allowing for easy cleaning and preventing contamination. They play a critical role in processes like filtration, separation, and controlled release of fluids, ensuring food safety and quality while maintaining the integrity of the food products throughout the processing operation.

Packaging machines
Packaging machines are specialized equipment used to automatically package food products into containers or packaging materials. These machines are designed to meet stringent hygiene standards, with smooth, easy-to-clean surfaces and food-safe materials to prevent contamination. They play a crucial role in ensuring the sanitary and efficient packaging of food items, maintaining product quality, and extending shelf life while adhering to food safety regulations in the processing industry. In many packaging machine components fluoropolymers are being used.

Pipes/Tubes
Pipes are tubular conduits made of food-grade materials, used to transport liquids or gases between different stages of the food production process. These pipes are designed with smooth, easy-to-clean surfaces and are typically free from crevices or dead spaces to prevent the accumulation of contaminants. By maintaining strict hygiene and sanitation standards, pipes ensure the safe and efficient transfer of food products and ingredients, promoting food safety and quality throughout the processing facility.

Pumps
A pump refers to a specialized mechanical device used to transfer fluids (such as liquids or viscous materials) within a sanitary environment. These pumps are designed to meet strict hygienic standards, ensuring they are easily cleanable, prevent contamination, and maintain food safety while handling sensitive food products in the processing industry. Elastomeric seals are applied in between the different materials to ensure leak-proof equipment. In many pumps fluoropolymers are being used.

Rollers
A roller refers to a cylindrical component typically made of stainless steel or other food-safe materials, used to convey or move food products along a processing line. Rollers are designed with smooth, easy-to-clean surfaces, and they play a crucial role in ensuring hygienic and contamination-free transportation of food items during various stages of food processing.

Rotors
Rotors are rotating components used in various food processing equipment, such as mixers, grinders, and pumps. These rotors are designed with smooth surfaces and made from food-grade materials to meet strict hygiene standards. They play a crucial role in mixing, grinding, or pumping food products efficiently and safely. Proper cleaning and maintenance of rotors are essential to prevent cross-contamination and ensure the production of high-quality and safe food products in the processing industry.

Scissors
Scissors are cutting tools with two opposing blades used to trim, cut, or portion food products during various stages of food production. These scissors are designed with smooth, easy-to-clean surfaces and made from food-grade materials to meet strict hygiene standards. Proper cleaning and

sanitation of the scissors are essential to prevent cross-contamination and ensure the safe handling and preparation of food items in the processing industry.

Seals (mechanical/static/dynamic)
Material between different components. Closure of an opening to effectively prevent the entry or passage of unwanted matter. (For EHEDG purposes, seals are fabricated from elastomeric materials.)

Dynamic seal The seal established between components that move relative to each other. The seal is formed using a combination of compression, pressure, and the geometrical shapes of the joined materials to create a seal at the interface of the components.

Seals are components used to prevent leakage and maintain airtight or watertight connections in mechanical systems, such as pumps, valves, and processing equipment. There are different types of seals, including mechanical seals (used for dynamic applications with moving parts), static seals (used for stationary connections), and dynamic seals (used for applications with relative motion between parts). These seals are designed with food-grade materials and smooth surfaces, ensuring easy cleaning and preventing the build-up of contaminants. Properly designed and maintained seals play a crucial role in ensuring the sanitary integrity of food processing equipment, promoting food safety, and preventing product contamination during the production process.

Sensors
Sensors are specialized devices or instruments used to detect and measure various parameters such as temperature, pressure, flow, or presence of certain substances in food processing equipment or environments. These sensors are designed with food-safe materials and smooth surfaces to meet strict hygiene standards. They play a crucial role in monitoring and controlling critical process variables, ensuring food safety, quality, and efficiency throughout the production process while maintaining a clean and sanitary environment in the processing facility.

Sliding plates
Sliding plates are flat, movable components used to regulate or control the flow of food products or ingredients within processing equipment. These plates are designed with smooth, easy-to-clean surfaces and made from food-grade materials to meet strict hygiene standards. Sliding plates facilitate the precise and hygienic movement of food items, ensuring efficient processing and preventing contamination during various stages of food production, thus promoting food safety and quality.

Stators
Stators refer to stationary components typically found in positive displacement pumps. They play a crucial role in maintaining a hygienic and sanitary environment by securely housing the pump's rotating components and preventing contamination or leakage during the food processing operations. These stators are designed with materials and surfaces that are easy to clean, resist microbial growth, and meet strict industry standards to ensure food safety and quality.

Tanks
Tanks are containers or vessels used to store, mix, or process food products in a sanitary and hygienic manner. They are constructed with smooth surfaces, easily cleanable materials, and designed to prevent the build-up of bacteria or contaminants. These tanks are critical in maintaining the integrity and safety of food products during processing, storage, and transportation within the food industry.

Tubes
Tubes refer to sanitary and hygienically designed piping or conduits used to transport liquids, gases, or other food products within the processing system. These tubes are constructed with materials that are easy to clean, resistant to corrosion, and meet strict industry standards to ensure the prevention of bacterial growth and contamination during the food processing operations. Properly designed and maintained tubes play a crucial role in maintaining the quality and safety of food products throughout the processing stages.

Utensils
Utensils are tools and implements used in the preparation, handling, and processing of food products. These utensils are designed with materials that are easy to clean, non-toxic, and resistant to bacterial growth. They play a critical role in maintaining food safety and hygiene by preventing cross-contamination and ensuring that the food processing environment remains sanitary and free from potential contaminants. Properly designed and maintained utensils are essential for producing safe and high-quality food products in the food industry.

Valves
Valves are essential components used to control the flow of liquids or gases in a sanitary and hygienic manner. These valves are designed with smooth surfaces, easily cleanable materials, and are free from crevices or dead spaces where bacteria can accumulate. They play a crucial role in ensuring the safety and integrity of food products during processing by preventing contamination and maintaining a sterile environment. Properly designed and maintained valves are essential for efficient and hygienic food processing operations within the food industry. Elastomeric seals are applied in between the different materials to ensure a leak-proof equipment.

Appendix 2 – Case Studies

Case study 1:

Use of Fluoroplastic Sealing elements in food production and transport

Key facts:

• Fluorinated polymers are used as gaskets in equipment for processing, transport, and storage

• Hot temperature processing e.g. aseptic processing is commonly used, where in many instance fluoroplastics, specifically PTFE are the only choice for sealing

• Stringent control on the number of leachable extracts that can be released into the media from the gasket exit, e.g., in Food applications, as mentioned in the above paper

Food processing and storage industries produce and use an array of aggressive media (such as strong acids) as cleaning and disinfectant agents and as additive to the final product where chemical compatibility issues dictate the utilisation of certain materials for sealing equipment. Many applications require sealing systems that can work at the extreme of pH; 0 to 14.

PTFE polymers are preferred due to their substantial chemical resistance to media attack, extremely low fugitive emission sealing characteristic as well as favourable mechanical properties such as creep resistance, stress retention properties, low friction characteristics - particularly in valve stem and rotary shaft sealing applications and where other materials and compounds do not perform to the same category of sealing integrity required from the industry. Virgin PTFE also has excellent permeability resistance and is having no or low leaching which make it critical for the food industry.

The options for alternative non-fluoropolymer-based sealing materials in these critical process sectors have proved unsatisfactory and unsafe. The unique properties of PTFE polymers are an essential component in the manufacture of gaskets and sealing components within the food processing sector and offer high integrity sealing of a broad range of chemicals protecting the environment from harmful and unintended emissions or leakage.

Case study 2:

Extract of EHEDG Guideline 48 on elastomeric seals and European Sealing Association (ESA) positioning paper.

Complex equipment and components are often used in food processing. The equipment and components are typically made from stainless steel. From a hygiene point of view, connections between components and equipment should be welded using methods described in EHEDG Guideline Documents No. 9 (Ref. 1) and No. 35 (Ref. 2) or by AWS Standards D18.1 (Ref. 3) or D18.3 (Ref. 4). However, this is not always technically possible. Some equipment needs to be readily accessible for cleaning, inspection and/or maintenance, hence assembly features (e. g. threads) need to be sealed to prevent product contact. Other machines incorporate moving parts that should be sealed (e. g. valve stems or plugs). Seals coming into contact with the product must be hygienically designed and must only be used within the range of the material specifications, otherwise they can pose a hygiene hazard.

The hygienic integrity of a seal changes over time, depending on operating conditions (e. g. wear, corrosion, degradation, shrinkage and swelling). An effective maintenance program relies on experience or qualification testing. Elastomer is also commonly referred to as 'rubber'; O-rings may be referred to as 'seals'; a coupling may be termed a 'joint' and the groove in which a seal is held may be known as its housing.

The choice of elastomer to be used in a given application is dependent on the operating conditions such as temperatures, pressures, processing media and the CIP/SIP-media which the seal will encounter in service. It has to be considered that members of the same family of elastomers can each have a number of different ingredients. EHEDG Doc. 32 (Ref. Error: Reference source not found discusses the behaviour of a variety of materials under a wide range of conditions.

Mechanical Seals which are used to seal rotating shafts as they enter the housing of pumps, centrifugal compressors, and agitators. The seals prevent gases and liquids from escaping in the space where there is relative motion between the shaft and the housing. Various mechanical seal technologies are used: Single spring seals, double seals, dry gas seals or wet oil seals all with significantly different emission characteristics.

Compression Packing is most commonly made of braided fibres and is used to seal valve stems and shafts of reciprocating compressors. Valves have been identified as a major contributor to emissions, primarily due to their extremely high usage. Modern fibres and construction methods allow sealing at extremely low emission levels.

Expansion Joints for Piping are used to provide a flexible connection between pipes flange connections and other equipment. The use of expansion joints can reduce the number of piping connections, eliminate stress on a pipe that can create leaks in bolted joints, and reduce stress on rotating equipment that could affect seal or bearing wear, thereby significantly contributing to the reduction of emissions in piping systems.

Elastomeric and Polymeric Seals. Typically, these are custom moulded or machined components (including “O” ring seals) manufactured from a whole host of deformable and resilient materials to seal liquids and gases in pressure containing systems. Frequently static but are also used between parts in relative motion such as hydraulic cylinders or valve stems, and continuous rotary motion such as marine and automotive drive shafts.

Section 17 of the Framework Regulation (Ref. 19(EC) No 1935/2004 demands traceability of all components, including seals, at least one stage backwards and one stage forward throughout the supply chain from raw material supplier to end user, in order to mitigate the related risks towards food safety.

It is recommended that the manufacturer’s in-house documentation records the process parameters, the selected raw materials and their batch numbers and a list of part numbers or dates of supply, as necessary to maintain this chain and the end user maintains these records for all food applications.

Appendix 3 - Literature

1) Henry, Barbara J. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. Integrated Environmental Assessment and Management. 2018, p. 316
2) Korzeniowski, S.H. et al. (2023), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, 19, 326-354, https://doi.org/10.1002/ieam.4646
3) OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. Series on Risk Management, 61. [Online] https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf
4) Gehrmann, H.-J. et al. (2023), Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions
5) Aleksandrov, Krasimir. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere. 2019, p. 898
6) Bougas, K., et al. (2020), Scientific and technical support for the development of criteria to identify and group polymers for registration / evaluation under REACH and their impact assessment. Final Report for the DG Environment, European Commission, Brussels, https://data.europa.eu/doi/10.2779/890644