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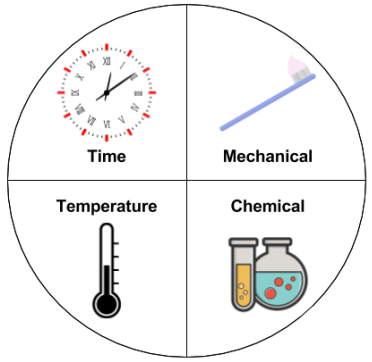
a Garlock Hygienic Technologies company

Leading Innovator of Sanitary Gaskets, Hoses, Hose Assemblies and Pump Parts

Video training:
Hygienic Design and Industry Standards

24.04.2020 – Webinar I

by Sascha Butter, Christoph Neuffer, Dominik Wiese



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A few notes

- All participants please **mute your microphones**
- Please feel free to raise **questions in the chat box**
- **Anonymous poll** by the end of the webinar
- We will **record this session** in order make it available online afterwards
- **Slides and related documents** will be made available online

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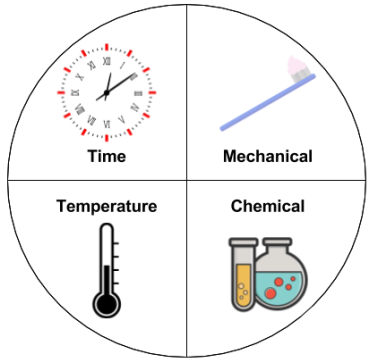

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Product Selection Guidelines

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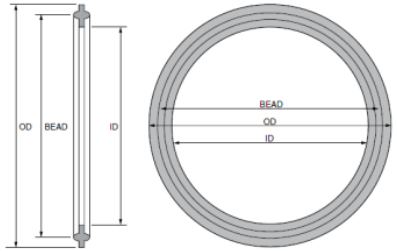
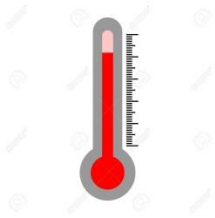
STAMP Gasket Selection

- Size:



- Temperature:



- Application:

Solid or Gas

- Media: See "***Chemical-Resistance-List2***"

- Pressure:

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STAMP Selection

1 = Excellent 2 = Good 3 = Acceptable 4 = Marginal 5 = Poor 0 = Do Not Use

Gasket Comments	Continuous Steam	Intermittent Steam	Pure Water Ambient	Pure Water Hot	Process Fluids Ambient	Process Fluids Hot	Variable Temperatures	Temperature Range
Tuf-Flex® Maintains seal with wide temperature variations. Has extended service life	1	1	1	1	1	1	1	-29°C (-20°F) to 149°C (300°F)
Tuf-Steel® Maintains seal with wide temperature variations. Has extended service life	1	1	1	1	1	1	1	-198°C (-320°F) to 288°C (550°F)
GYLON BIO-PRO® Modified and restructured PTFE material, pre-formed and stress controlled	1	1	1	1	1	1	1	-268°C (-450°F) to 260°C (500°F)
GYLON BIO-PRO® PLUS Best in class performance for chemical compatibility, seal-ability, creep and cold flow	1	1	1	1	1	1	1	-268°C (-450°F) to 260°C (500°F)
PTFE Wide temperature variations and may cause leakage at ΔT	1	1	1	1	1	1	3	-37°C (-35°F) to 260°C (500°F)
Silicone (platinum) Very flexible low temperature	2	2	2	2	2	2	1	-40°C (-40°F) to 232°C (450°F)
FKM Fluoroelastomer Acceptable for steam applications	2	2	2	2	2	2	2	-34°C (-29°F) to 204°C (399°F)
EPDM (peroxide cured) Low pressure steam only	3	3	3	3	3	3	3	-34°C (-29°F) to 149°C (300°F)
Buna Not recommended for strong acids and ozone	0	0	5	5	5	5	5	-34°C (-29°F) to 93°C (199°F)

Please check file: "***RF_Validation_Solutions_Brochure_2020_EN***"

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Product Selection Overview

26 Brookfield Drive • Sparta, New Jersey 07871 USA
+1-866-4-72-2694 • +1-973-729-2215 Fax
sales@rubberfab.com • www.rubberfab.com

Product/Attribute	GYLON® BIO-PRO PLUS™	GYLON BIO-PRO®	Buna	FKM	EPDM	Silicone	PTFE	Tuf-Flex®	Tuf-Steel®	PTFE/EPDM Envelope	PTFE/FKM Envelope
Temperature Range	-260 to +260°C	-260 to +260°C	-40 to +135°C	-30 to +205°C	-28 to +150°C	-40 to +230°C	-73 to +260°C	-20 to +260°C	-200 to +288°C	-30 to +150°C	-30 to +170°C
Pressure Range	up to 55 bar	up to 55 bar	Clamp****	Clamp****	Clamp****	Clamp****	Clamp****	Clamp****	Clamp****	Clamp****	Clamp****
Vacuum	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Chemical Resistance	Universal*	High	Low to Medium	Medium to High	Medium	Medium	Universal*	Universal*	High	Universal*	Universal*
Material	100% PTFE	PTFE + Pigment + Filler	100% Buna	100% FKM	100% EPDM	100% Silicone	100% PTFE	PTFE + EPDM	PTFE + 316SS	PTFE/EPDM	PTFE/FKM
Traceability	Yes	On Demand	On Demand	On Demand	On Demand	On Demand	On Demand	On Demand	On Demand	On Demand	On Demand
CIP Processes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SIP Processes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dimensional Stability	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Easy removal/non-stick	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Shelf Life	Unlimited	Unlimited	10 Years	10 Years	10 Years	10 Years	10 Years	10 Years	10 Years	10 Years	10 Years
Service Life	Unlimited**	Unlimited**	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***	Application Dependent***
TA-LUFT + Blowout	Yes	No	No	No	No	No	No	No	No	No	No
FDA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
EC1935	Yes	Yes	No	No	No	No	No	No	No	No	No
USP Class VI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Phthalate Free	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Silicone Free	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
BAM Tested	Yes	Yes	No	No	No	No	No	No	No	No	No
ADI Free	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hydrocheck	No	Yes	No	No	No	No	No	No	No	No	No
3A 60-63	TBD	No	No	Yes	Yes	Yes	Yes	No	No	No	No
3A 18-30	No	No	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1
3A 20-27	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hygienic Design per EHEDG	Yes	No	No	No	No	No	No	No	No	No	No
NSF 61	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
62.Bfr	Yes	No	No	No	No	No	No	No	No	No	No
Application	Pharma, Food, SIP/CIP, Hygienic Design, Ultra-low Adhesion, High Purity Demands, Sustainable Cleaning	Pharma, Food, Rough SIP & CIP, Well Known and Proven Gasket	Pharma, SIP/CIP, Good Chemical Resistance	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP	Pharma, Food, Rough SIP & CIP, Well Known & Proven Gasketing Material	Pharma, Food, Rough SIP & CIP, Well Known & Proven Gasketing Material	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP	Pharma, Food, High Chemical Resistance & Temperature Range, SIP, CIP

*Except certain alkali metals and fluorinating agents **Dependning on application parameters ***Service life is dependent upon specific application and assessment by the customer ****Clamp

Please check file "***RF_200219_V2_Product_Selection_Guide***"

Hygienic Design

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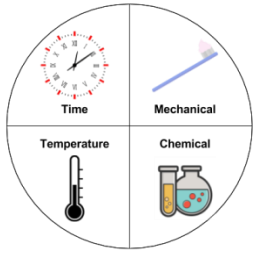
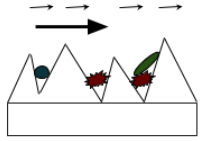
Hygienic Design Criteria

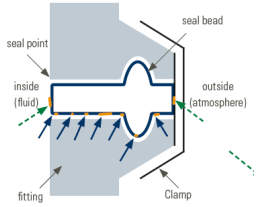
- Cleanability (Cleaning in Place – CIP, Sterilization in Place SIP)



- Surface nature and properties



- Dimensional Stability



- Certifications and Regulations

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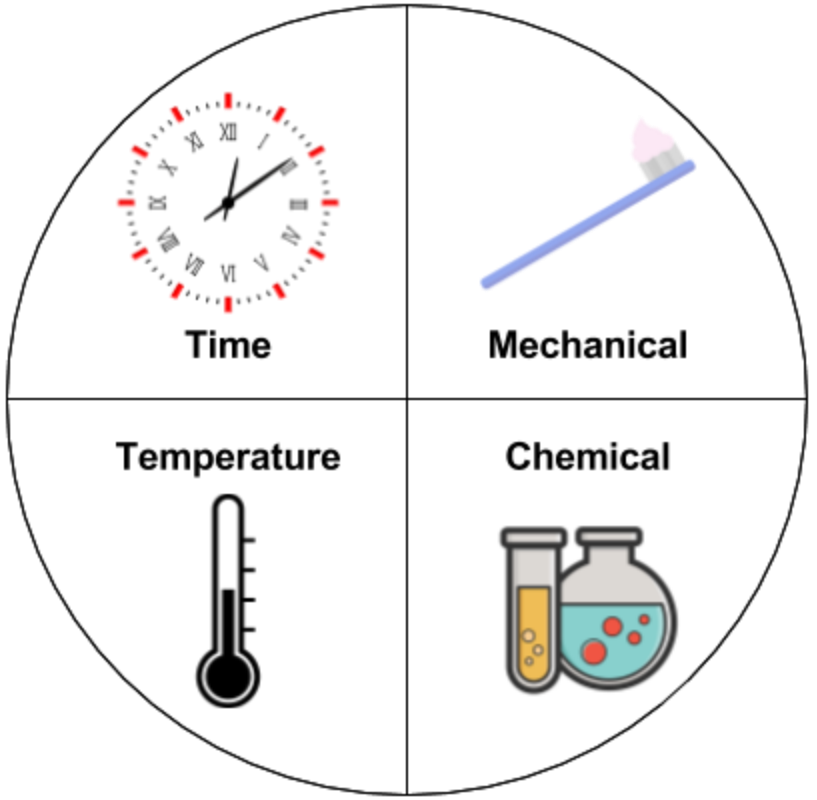
CIP – Cleaning in Place

Challenges:

- Fast and effective cleaning cycles
  - High temperatures
  - High pressures and low rates
  - High chemical concentration
  - Low time and amount of cycles

- Stricter regulations
- Demanding application parameters



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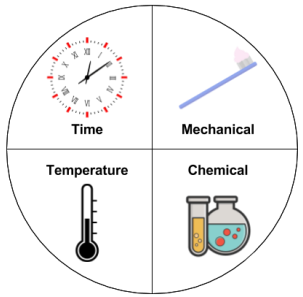
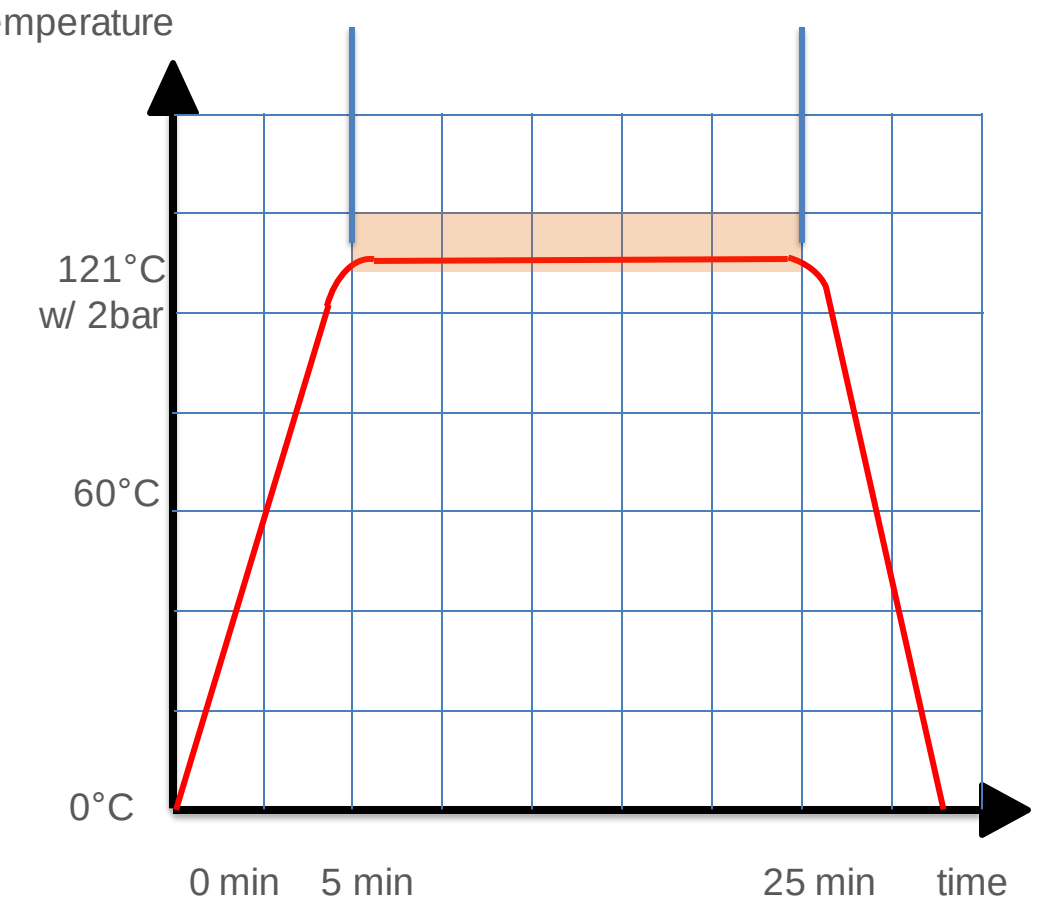
SIP – Sterilization in Place

Challenges:

- Fast and effective sterilization types
  - Irradiation
  - Chemical sterilization
  - Sterilfiltration
- Steam Sterilization
  - High Pressure
  - Longer Cycle
  - High Temperature



- 20 min's at 121°C with 2 bar



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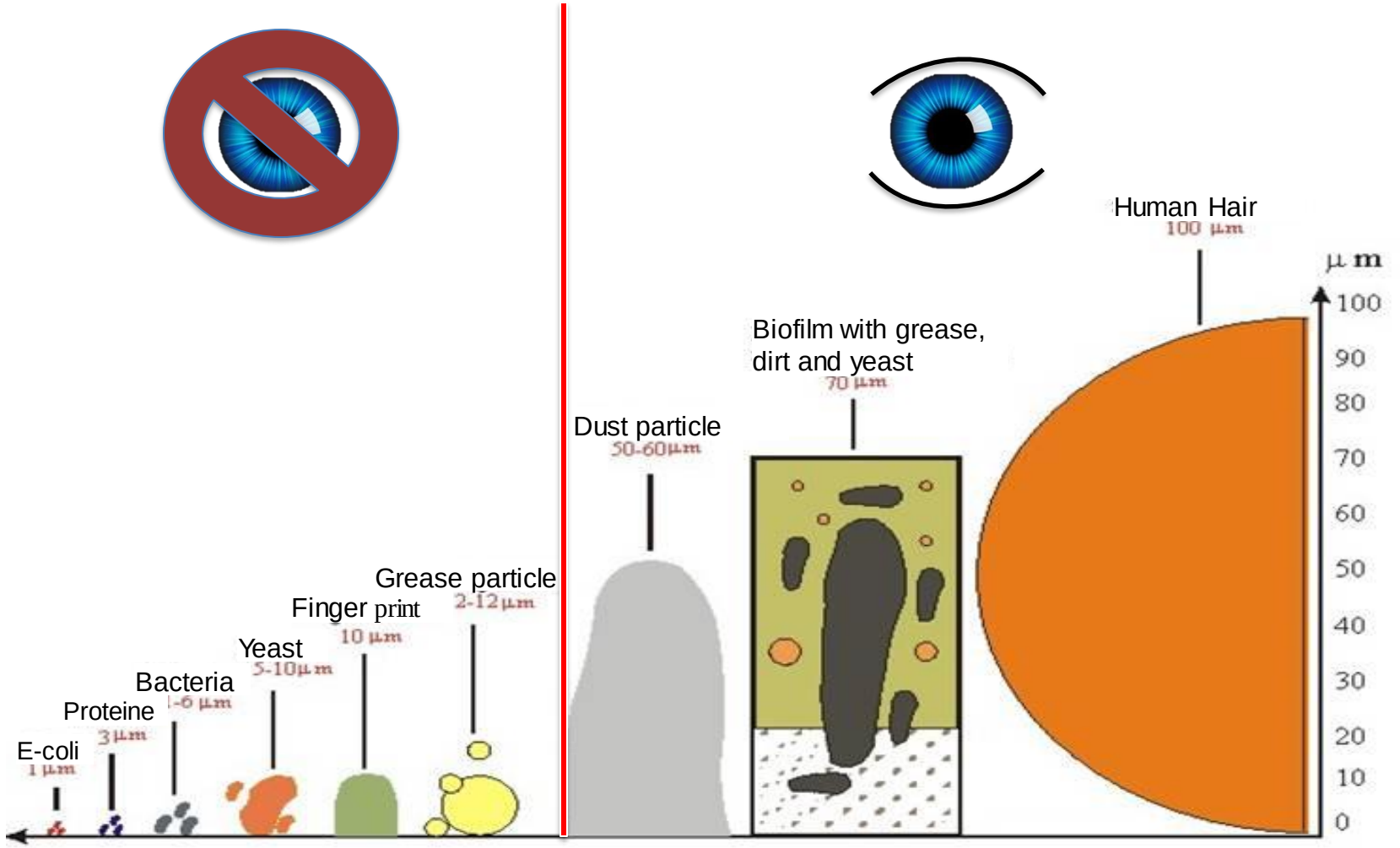
Invisible

Visible



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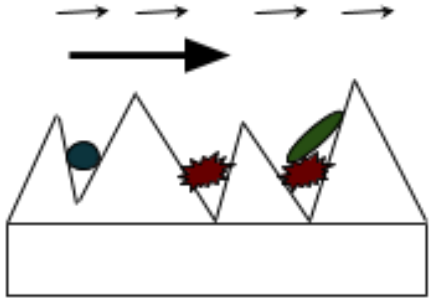
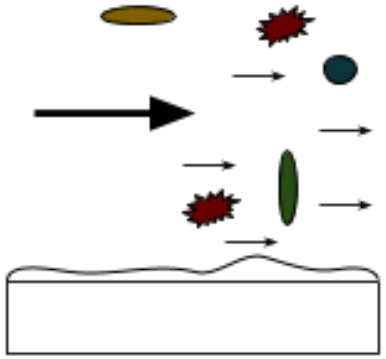
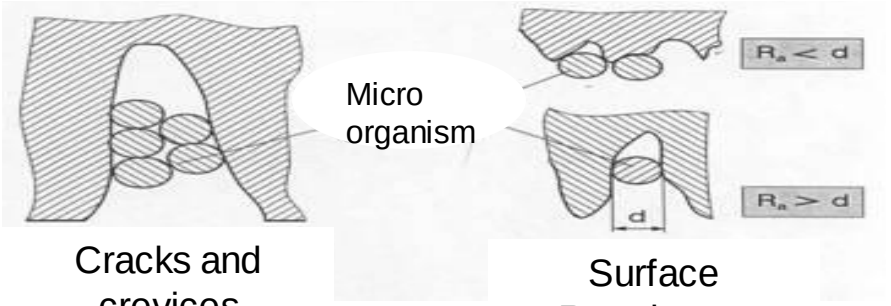
Gasket Surface

- A rough surface with a relatively high free surface energy causes an entrapment risk







Cracks and crevices

Surface Roughness

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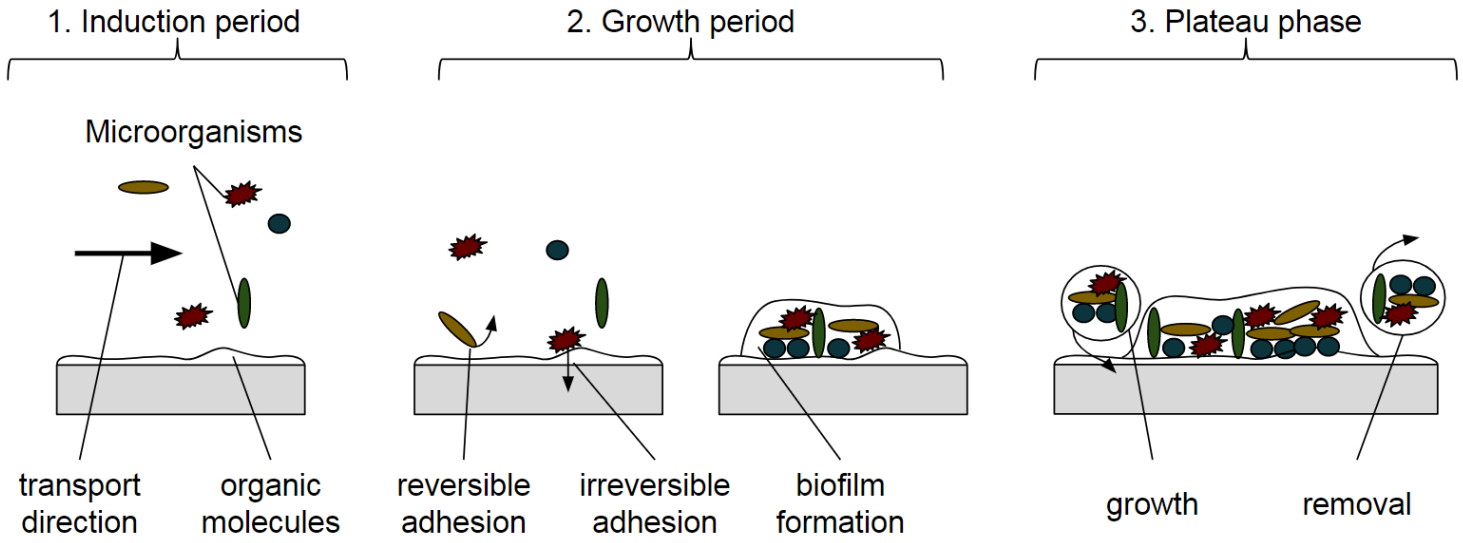
Biofilm



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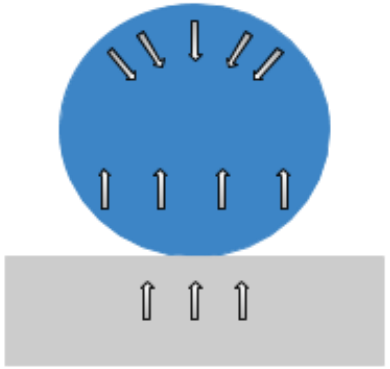
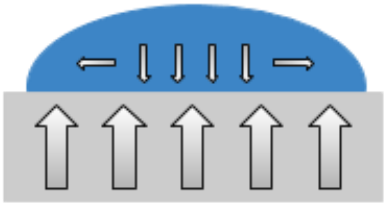
Surface Energy

Hygienic Design:

- Excellent dimensional stability
  - Reduced cold flow
  - No Intrusion/Recess -> Dead-space free design
- Smooth surface finish (Cleanability better than of 316 SS)
- Anti-stick surface (Like ice on wet ice)
- Extremely low surface energy (≤ 18,5 mN/m at 20° C)



Solid with **low** surface energy



Solid with **high** surface energy

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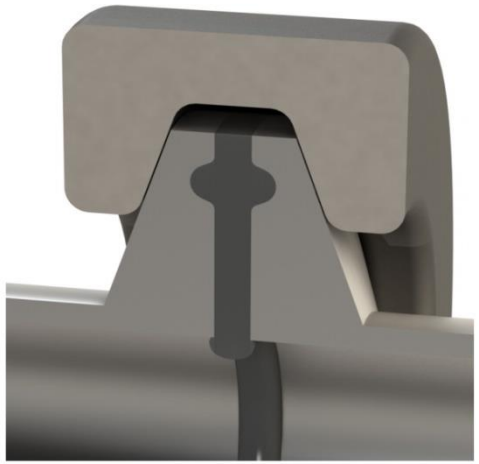
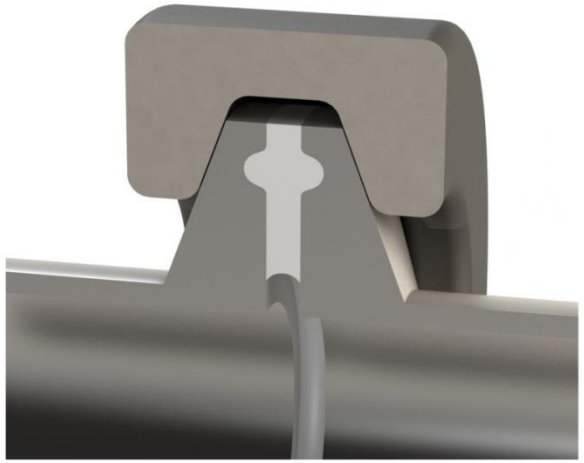
Dimensional Stability

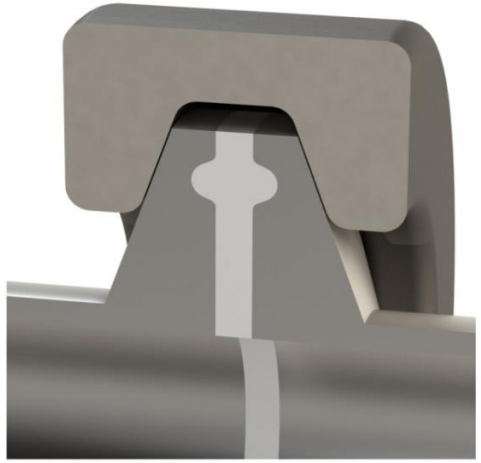
ID - Intrusion



ID - Recession



Smooth Bore



- Product accumulation
- Bacterial build-up

- Easy cleaning
- Dimensional stability

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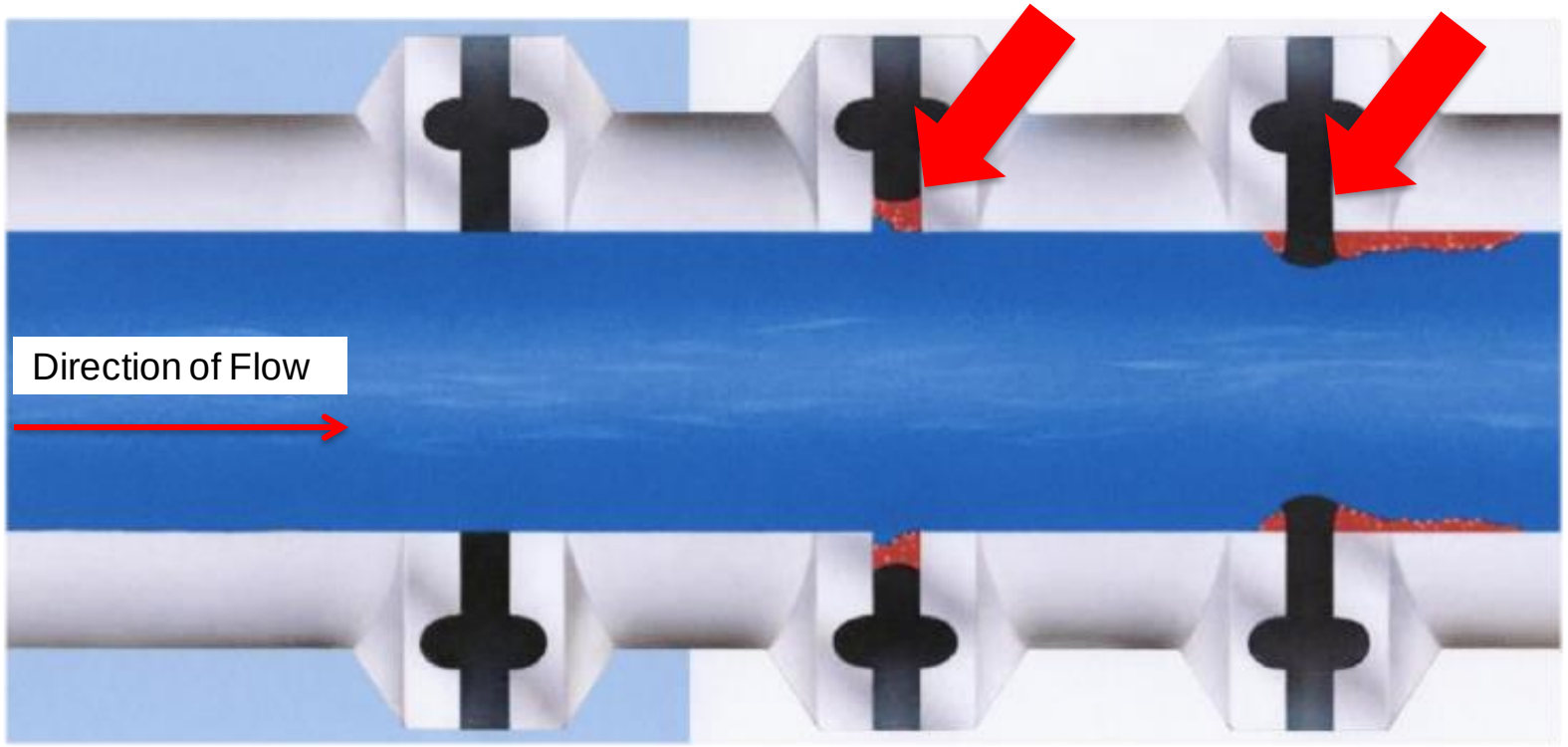
Intrusion and Recession



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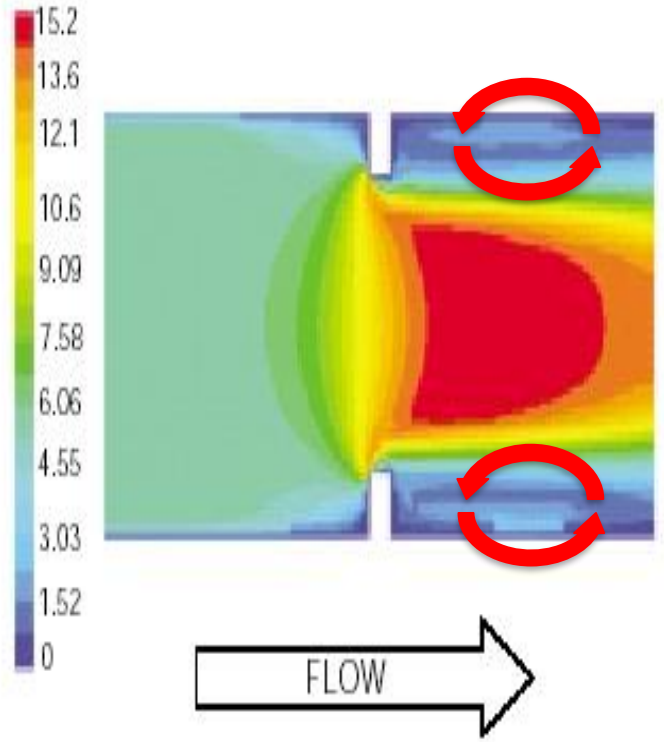
Dimensional Stability

- Difficulty in cleaning, very costly
- Longer cleaning cycles

- Cross contamination, very costly

- Product Hold-Up, very costly
- Restriction in flow
- Creates Dams- turbulences
- Higher velocity created



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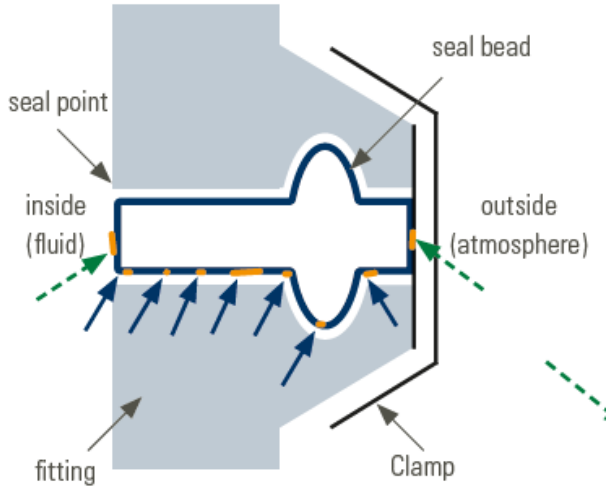
Sealing Points



- Maintaining the **ideal sealing point** is critical to prevent leakage and entrapment
- Heat and chemicals over time cause swelling of the gasket (expand/contract)
- Compression of gasket is critical to seal

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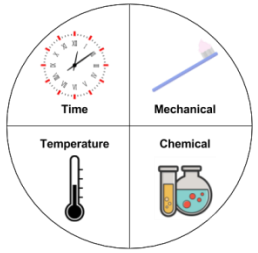
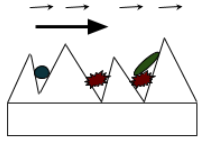
Summary Hygienic Design

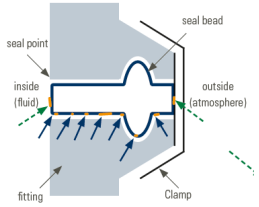
- Cleanability (Cleaning in Place – CIP, Sterilization in Place SIP)



- Surface nature and properties



- Dimensional Stability



- Certifications and Regulations

Please check file "***Sealing Design White Paper***"

Industry Certificates and Standards

Regulations, Standards, Associations

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In-House Testing Capabilities

Chemical lab

Compound lab

Physical lab

Functional lab

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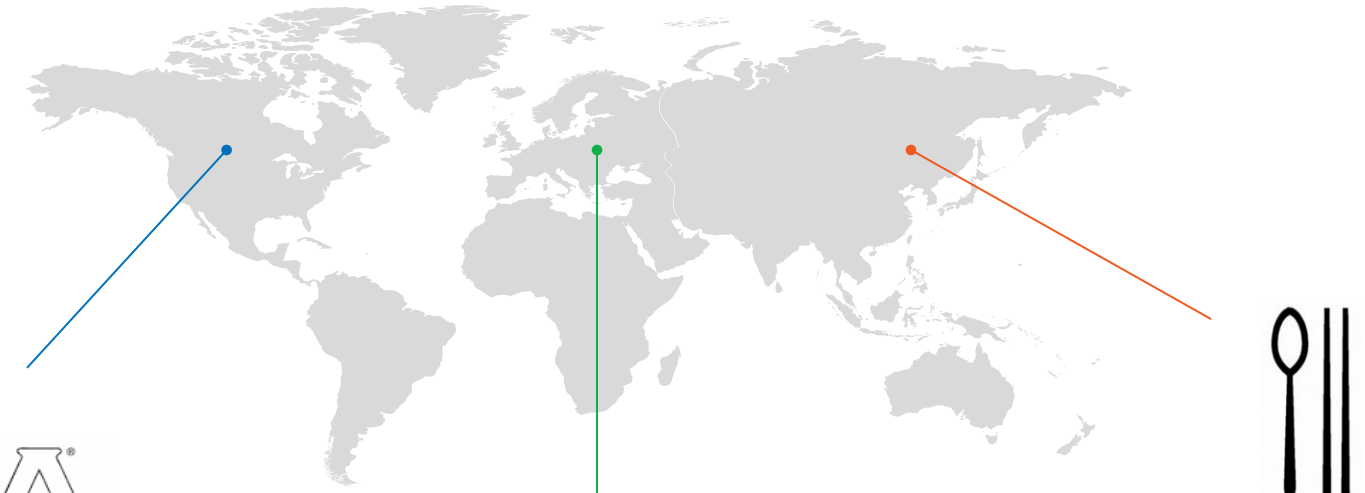
Overview of Regulations



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Leachables and Extractables

Definition of extractables acc. to ASME BPE Standard 2012:

- Extractables are chemicals that can be removed from final articles using appropriate solvents (eg. polar and non-polar) for the purpose of identification and quantification of potential leachables.

- Leachables are chemicals that migrate from the final article into the process fluid of interest (eg. water, buffered solutions, drug product, etc.) under normal and/or accelerated conditions (typically exposure time and/or temperature). Leachables are typically a subset of extractables, but can also be created as a result of chemical reactions with other leachables and/or components.

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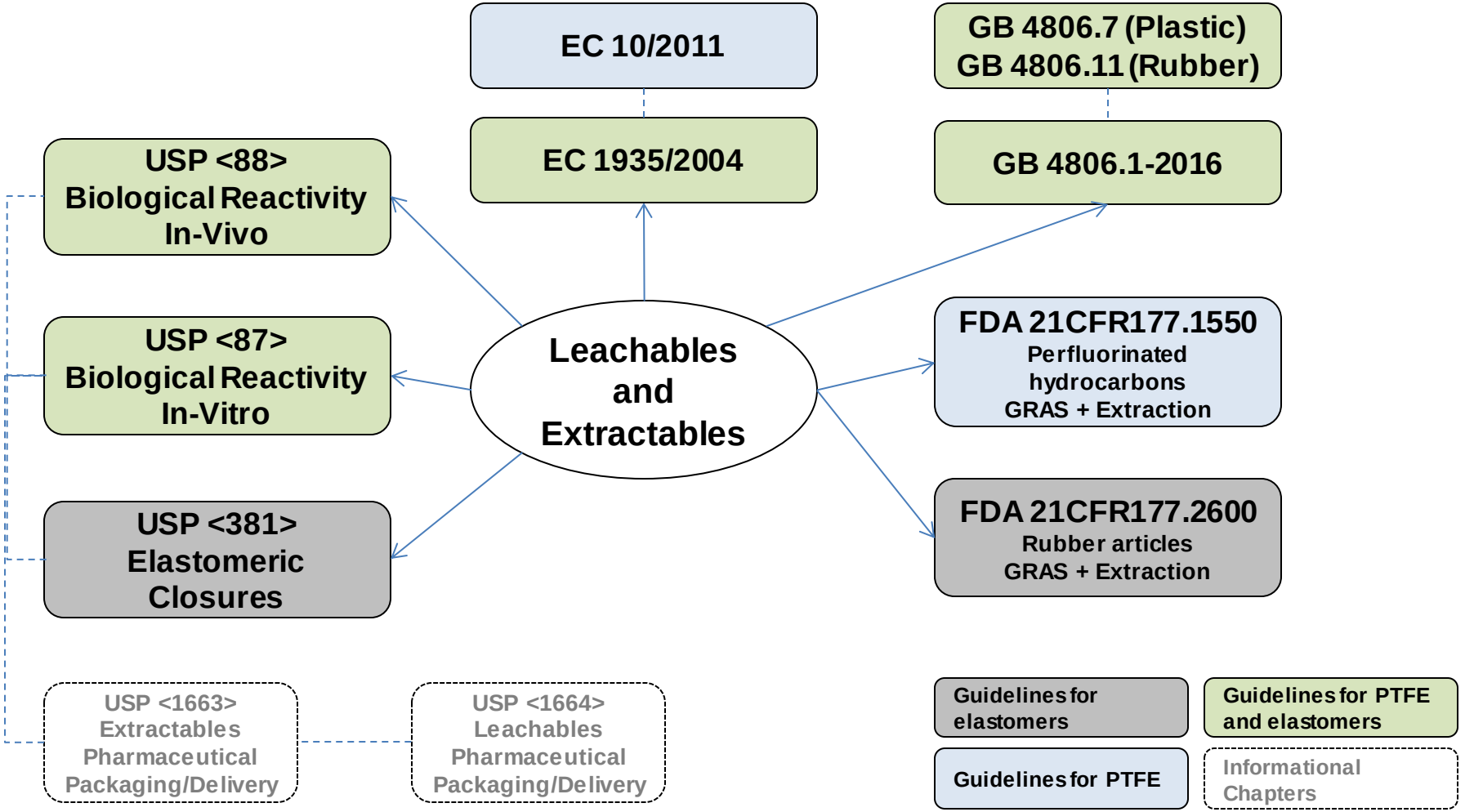
Extraction Testing



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EC 1935/2004 – Food Contact Materials

Framework Regulation (EC) 1935/2004

(GMP) Regulation EC 2023/2006

Material Standards

In place for:

- **Plastic - EU No 10/2011**
- Recycled Plastic
- Active and intelligent materials
- Ceramics
- Regenerated Cellulose

NOT in place for:
Including:

- Adhesives
- **Rubber (FDA, BfR, etc.)**
- Glass
- Metals and alloys
- Ion ecxhange resins
- Paper and boards
- Printing inks
- Wood
- Textiles
- Lacquers/coatings
- Waxes

Restriction of substances acc. to EC No 1895/2005

- Nitrosamines
- BADGE, BFDGE & NOGE
- Bisphenol A

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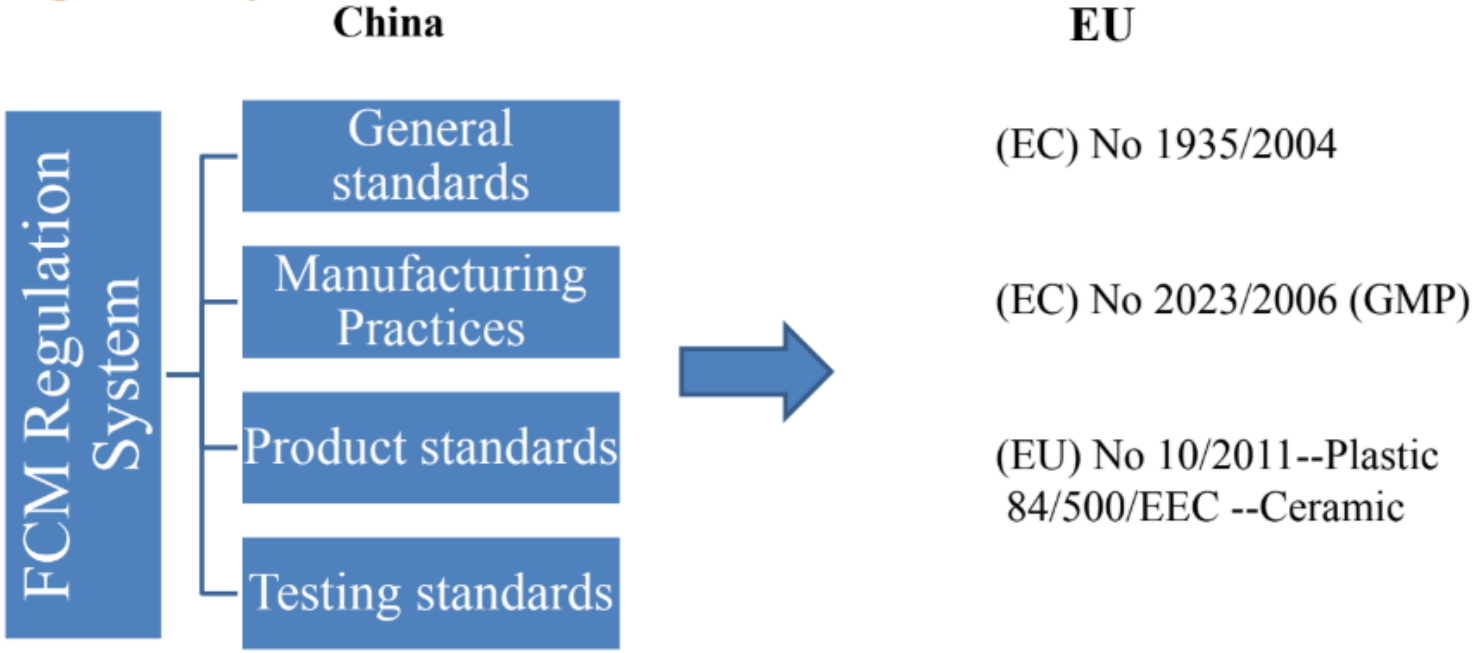
CHINA Food Contact Regulation

The frame of new China FCM regulation system is similar with EU regulation system



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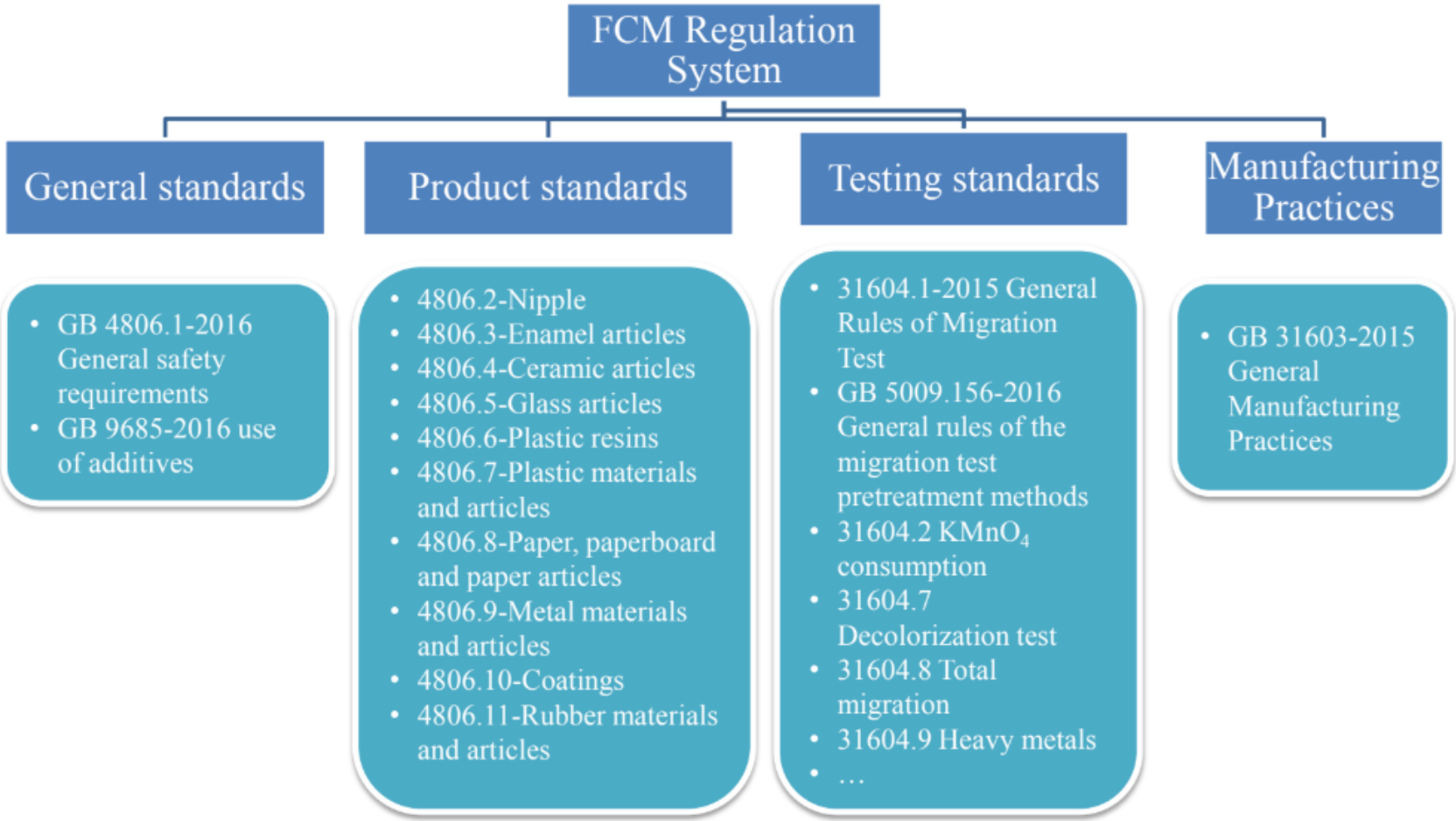
CHINA Food Contact Regulation



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FDA – Food and Drug Administration

- Government agency within the US Department of Health and Human Services responsible for enforcing the Federal Food, Drug and Cosmetic Act to ensure consumers' health and safety.
- Although the jurisdiction of the FDA is restricted to the United States, FDA regulations are commonly adopted as international control standards.
- **Title 21** is the portion of the **Code of Federal Regulations** that governs food and drugs within the United States for the Food and Drug Administration.

Standard	Reference
Sections 174 to 178	Dedicated to additives in direct contact with foodstuffs
21CFR177.2600	Rubber articles intended for repeated use
21CFR177.1550	Perfluorocarbons (PTFE products and compounds, FEP, etc.)
21CFR177.1520	Olefin based resins
21CFR178.3297	Colorants for polymers (e.g. fillers)
21CFR170.30	Resinous and polymeric coatings (including branding ink)

USP – United States Phamacopoeia

- A scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.
- USP's drug standards are enforceable in the United States by the Food and Drug Administration, but also used in more than 140 countries.
- USP defines six plastics classes, from I to VI (VI remaining the strictest).

Standard	Reference
Class VI	A plastic resin material that has passed Class VI certification is expected to be more likely to produce favorable biocompatibility results. Compounds must be made from ingredients with clear histories of biocompatibility that meet tight requirements for leachates.
Class VI Part 87 Testing	Also called cytotoxicity, is a complimentary in vitro test that measures the quality of the test substrate to be toxic to cells.
Class VI Part 88 Testing	In vivo animal test designed to evaluate plastics and elastomeric materials for use in drug processing equipment.

EPDM USP VI <87> Test Report

Silicone USP VI <88> Test Report

3-A Sanitary Standards, Inc.

- An independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries.

Purpose	Constituency
Representation	Three stakeholder groups – Regulatory sanitarians, equipment fabricators, and processors
Goal	Protect consumable products from contamination and ensure that all product surfaces can be cleaned
Compliance	Complies with the American National Standards Institute (ANSI) Essential Requirements: Due Process Requirements for American National Standards

- A prerequisite for 3-A approval is that the seal material already fulfills the FDA requirements. 3A standards include:

Standard	Reference
18-03	Elastomer seals
20-27	Perfluorocarbons (PTFE products and compounds, FEP and PFA resins)

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Plasticizer free

Description:

- Plasticizers like e.g. **Phthalates, Bisphenol** etc. are synthetic chemicals widely used in a variety of consumer products (e.g. medical devices, food wrap, building materials, children's toys, etc.).

- They are also used as solvents in many applications and in cosmetics to hold fragrance, reduce cracking of nail polish, reduce stiffness.

- Most plasticizers have been identified as reproductive and developmental toxicants, though their toxicity varies somewhat depending on the specific phthalate structure.

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ADI - Animal derivatives ingredients

Description:

- Concern about contamination of animal-derived ingredients by pathogenic agents during processing
- Animal-derived materials will not only harbor but often support growth of pathogens, and accordingly should assure appropriate control over the handling and processing of these materials.
- Pathogenic agent contamination includes bacteria, molds, viruses (e.g. TSE/BSE), protozoa, parasites, and prions.

ASME BPE

- This ASME Standard provides the requirements applicable to the design of equipment used in the bioprocessing, pharmaceutical and personal-care products industries, as well as other applications with relatively high levels of hygienic requirements.
- Covers materials, design, fabrication, inspections, testing and certification.
- Leading standard on how to design and build equipment and systems used in the production of biopharmaceuticals.

Standard	Reference
SF: Product Contact Surface Finishes	Defines requirements for surface finish acceptance criteria for metallic and polymeric materials
SG: Sealing Components	Provides requirements for sealing components: seals, valves, and fittings and defines the different types of static seals—hygienic unions, o-rings, and other static seals

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ASME BPE

- Three Points are especially important for gaskets their materials and their usage

ASME BPE 2019	Reference
Static Seal Performance SG-4-2	Upon installation a hygienic static seal shall provide a substantially flush interface. Hygienic seals shall meet and be designed by intrusion categories I or II
Surface roughness SF-3.4-1	Ra Regardings for Polymeric Process Contact Surfaces: Surface designation classes with minimum and maximum Ra for contact surfaces.
Simulated combined CIP and SIP Testing J-1.2.2	ASME BPE 2019 explains the testing of CIP and SIP Testing: The Testing cycles should occur without intervention (retorquing of clamps or fasteners)

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Feedback and outlook

- Feedback in Microsoft Teams chat area – poll for satisfaction
- Feel free to address additional feedback in regards to content, style of presentation, presentation skills of referents or similar by mail
  - Dominik Wiese – Area Sales Manager – dwiese@rubberfab.com
  - Sascha Butter – Product Manager – sbutter@rubberfab.com
  - Christoph Neuffer – Application Engineer – cneuffer@rubberfab.com
- Training handout
- Webinars
  - Webinar 01: Gasket Selection / Hygienic Design / Certification
  - Webinar 02: Gaskets and accessories
  - Webinar 03: European hose range