

Hygienic Seal Design with Elastomers

3-A Equipment and Beyond

Applying 3-A Principles to Food & Beverage Processing Environments
Bloomington, Tuesday, May 2, 2017

Company profile



- Rubber compound development
- Mixing of compounds
- Moulding of rubber parts
- Technical support and sales
- 220 employees DK and CN



Company profile



Drinking Water
Food
Healthcare
Technical Products

HIGH PERFORMANCE
RUBBER COMPONENTS
- for demanding applications



Company history

1975: Founded, based on valves for potable water

1980: Food. SOP's for QA/QC. Full traceability.

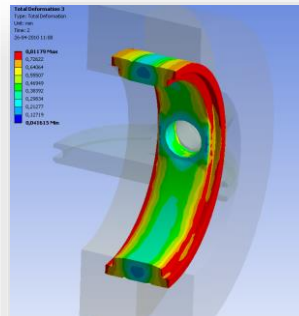
1991: ISO 9001 and ISO 14001

2002: QS 9000 (later TS 16949) and OHSAS 18001

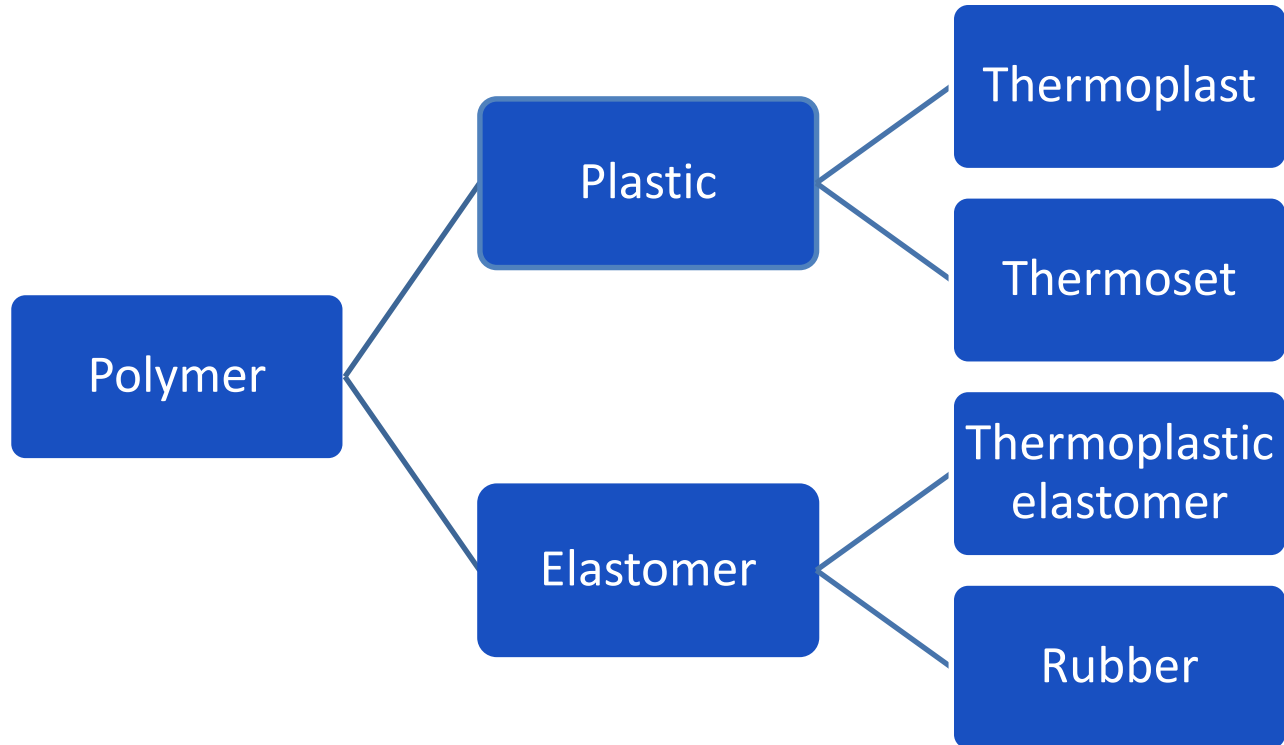
2004: AVK Sealing Technology in China

2009: 3-A Sanitary Standard (18-03)

2012: Medical Device facilities



Definitions



Rubber polymer chemistry

**Monomers =
building blocks**

Ethene
(E)

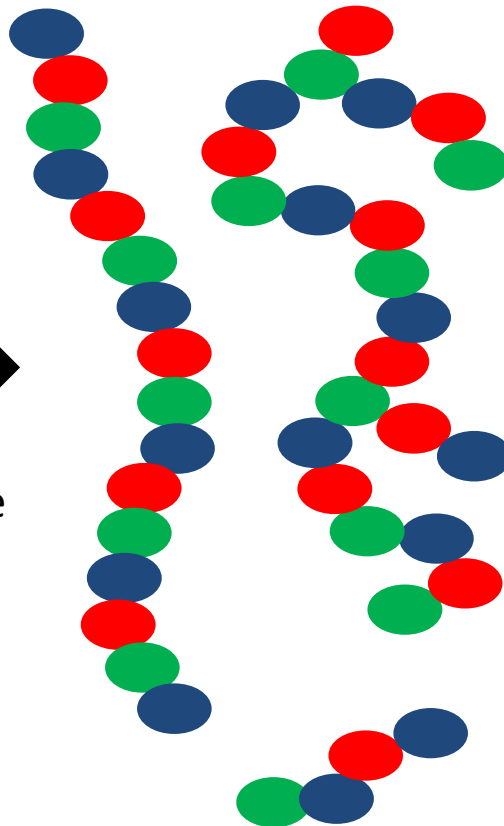
Propene
(P)

Diene
(D)

Polyme-
rization

Catalyst
Pressure
Temp.
Time

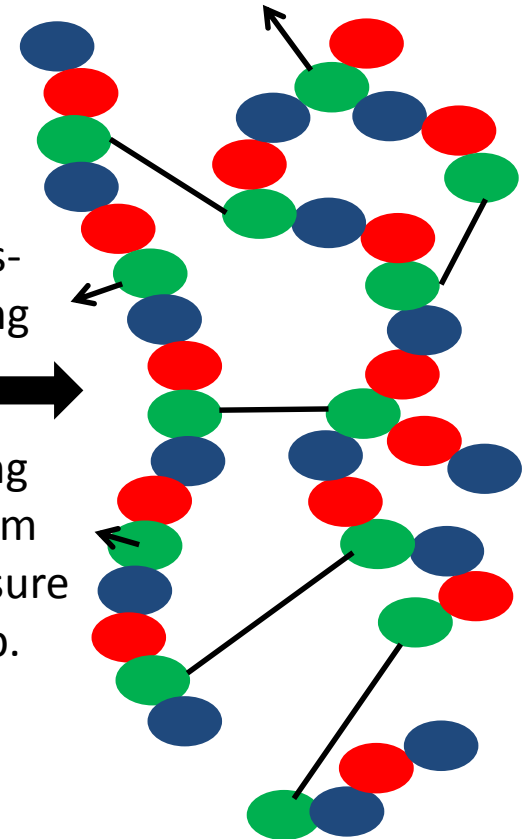
**Polymers =
Spaghetti structure**



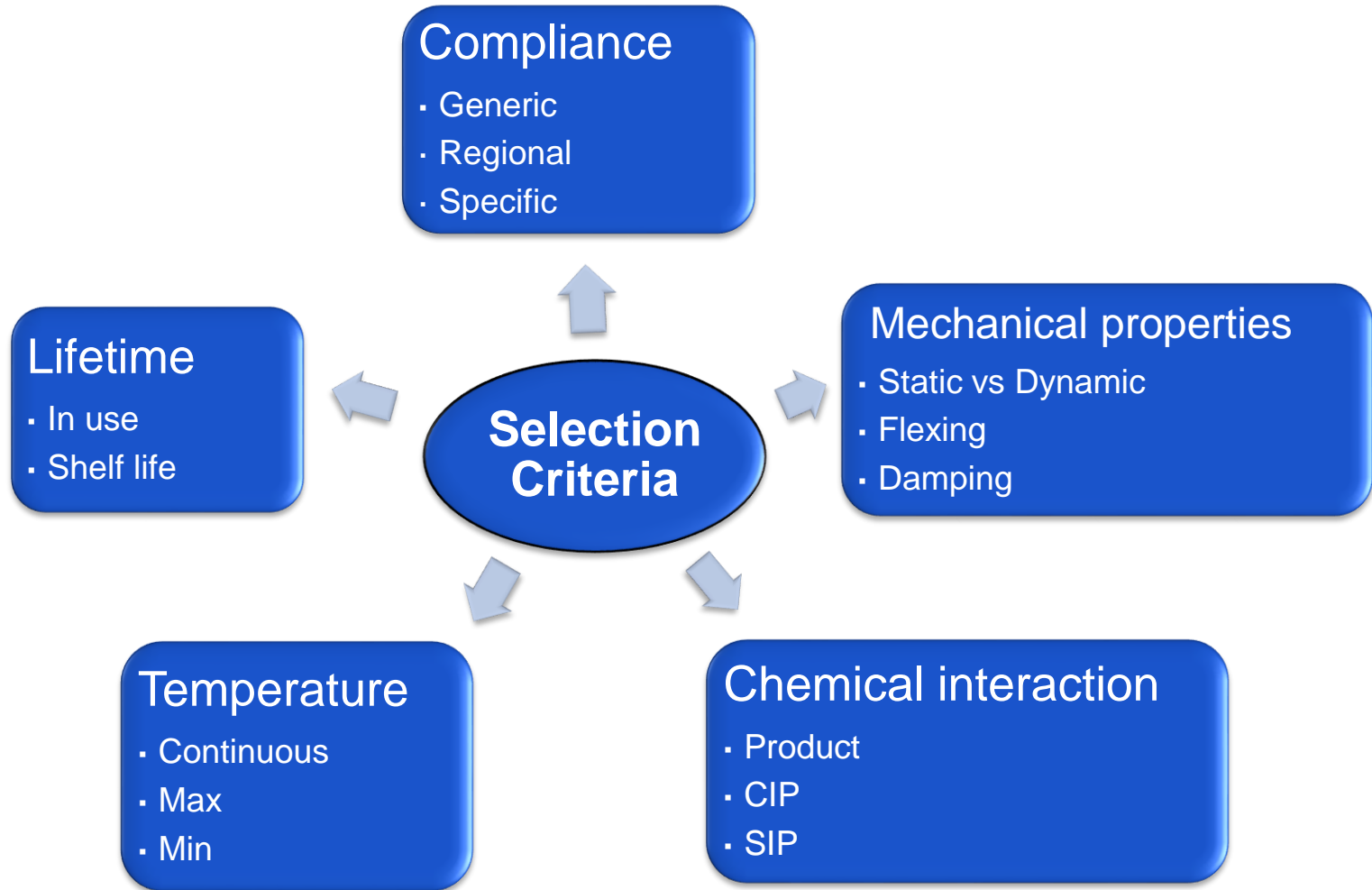
Cross-
linking

Curing
system
Pressure
Temp.
Time


**Rubber =
3D flexible structure**



Selecting rubber material



Food Regulation and Compliance

Europe	USA	China	ROW
EC1935:2004 - Traceability - GMP2023:2006 - 93/11/EEC (for teats only) - (EU/10/2011)	FDA 177.2600 - GRAS 3-A Sanitary Standard (18-03) (USP Class VI)	CFHL - GB4806.1:2016 - GB9685:2016 - GB5009.64:2003 (under revision)	South America: GMC 54/97 GMC 28/99
DE: BfR XV and XXI			AU/NZ: FSANZ Code
FR: Arrêté 9.11.1994 Arrêté 09.12.2006			JP: FSL 233/1948, a16 Vol.: Pos. List+migr
IT: DM 21/3/73			IL: Kosher
NL: RVG Chapt. 3			KR: FSA
DK: Bek. 149/2009 (Bek. 822/2013)			
SE: Order: SIVSFS Vol.: Normpack			
CZ, HU, RO, SK, SI			

Food Regulation and Compliance by AVK



CERTIFICATE

AVK GUMMI A/S, hereby certifies that our rubber compounds
are in compliance with the following regulations:

GMP	Good Manufacturing Process in accordance with 2023/2006 EC
REACH	In accordance with regulation EC 1907/2006. Candidate List of Substances of Very High Concern (15.06.2015) Substances listed in Annex XIV (14.08.2014) Substances listed in Annex XVII (08.05.2014)
Bisphenols	Do not contain Bisphenols as described in 1895/2005/EEC. BPA, BADGE, BFDGE, NOGE
Phthalates	Do not contain phthalates
RoHS + RoHS 2	In accordance with the Directive 2002/95/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 JANUARY 2003 and Directive 2011/65/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011
ODS	Do not contain Ozone Depleting Substances. In accordance with the Regulation EC 1005/2009 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 SEPTEMBER 2009 and Regulation EC 2037/2000 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 29 JUNE 2000.
ADI free	Do not contain any substances originating from humans or animals.
Hazardous Materials	Do not contain any hazardous substances as described in the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009
Conflict Materials	In accordance with US Law: "Dodd Frank Wall Street Reform & Consumer Protection Act", sec 1502, of 21.07.2010.

Yours sincerely,
AVK GUMMI A/S


Henrik Pedersen
R&D Manager


Anders G. Christensen
Sales and R&D Director

02.07.2015

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nr. 55 37 53 13



ISO 14001
OHSAS 18001
ISO 9001
TS 16949



CERTIFICATE

AVK GUMMI A/S, hereby certifies that our EPDM rubber compound

EAF-75

meets the following regulations:

FDA 21 CFR 177.2600	Rubber articles intended for repeated use in contact with foods. Aqueous and fatty foods: EAF-75 meets the specifications (extraction in distilled water and n-hexane) regarding repeated use in contact with aqueous and fatty foods.
3A Sanitary Standards	For multiple-use rubber and rubber-like materials used as product contact surfaces in dairy equipment for low-fat applications, number 18-03: Class II
EC 1935/2004	AVK GUMMI A/S confirms the harmlessness for human health as required in EC 1935/2004 and in addition, AVK GUMMI A/S confirms that the requirements for traceability have been fulfilled.
USP Class VI	USP and ISO Systemic Toxicity study was tested and approved according to the requirements. The extracts were prepared respectively at 70°C for 24 hours.

Yours sincerely,
AVK GUMMI A/S


Henrik Pedersen
R&D Manager


Anders G. Christensen
Sales and R&D Director

21.09.2015

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ISO 14001
OHSAS 18001
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TS 16949

Compression set



Poor resistance to compression set leads to permanent deformation.

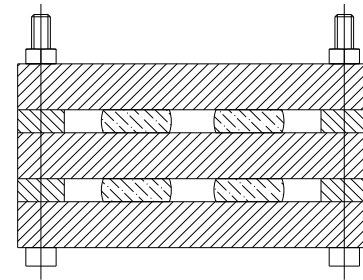
- Leakage and cross contamination
- Reduced cleanability due to reduced compression between gasket and housing (crevice)

$$\text{Compression Set (S)} = \frac{d_0 - d_1}{d_0 - d_s} \times 100\%$$

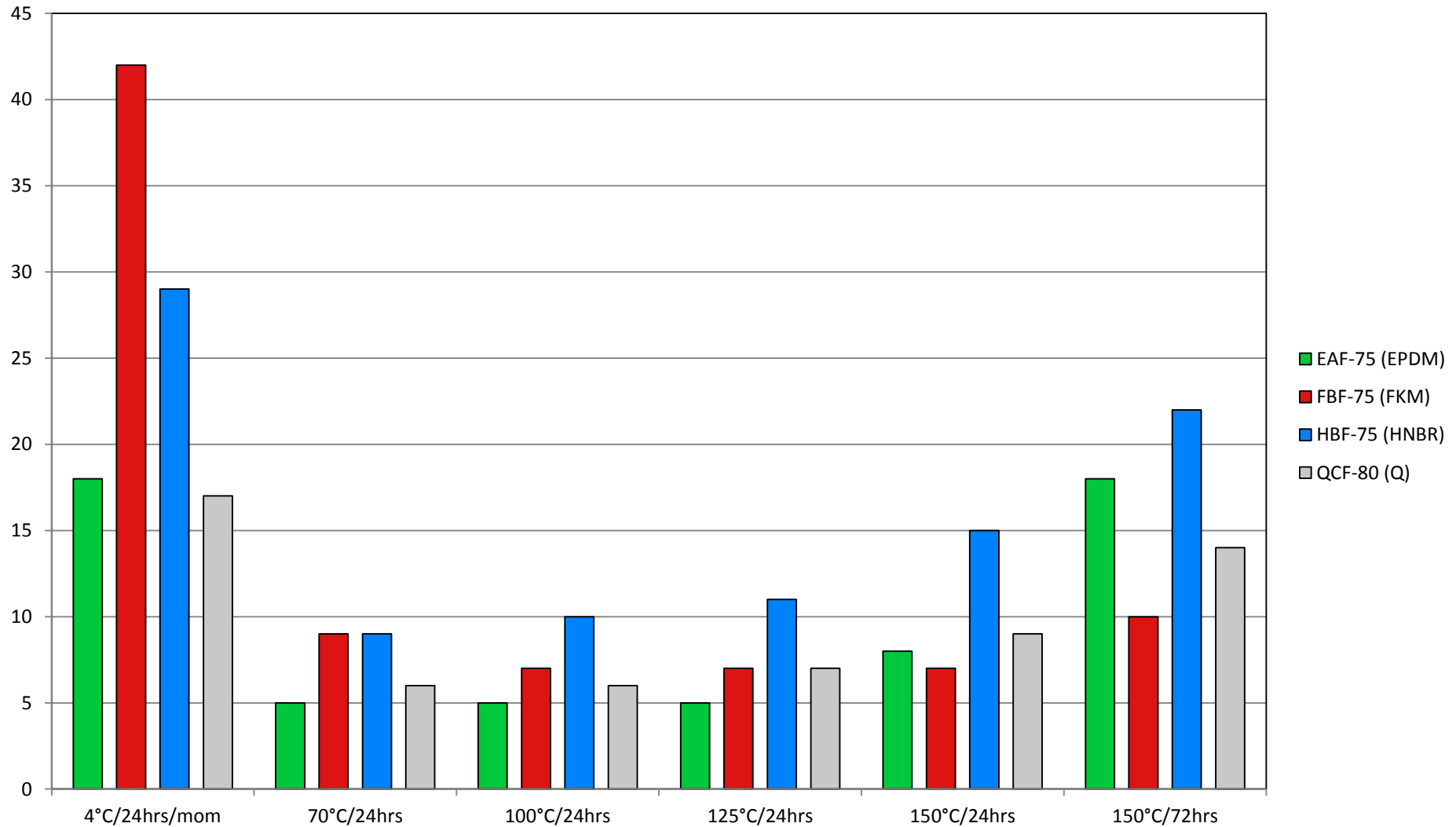
d_0 = Original thickness of the test specimen

d_1 = Thickness of test specimen after testing

d_s = Thickness of test specimen in compressed condition



Compression set (%) vs. time and temperature



Chemical degradation and erosion



Wrong selection of rubber can cause:

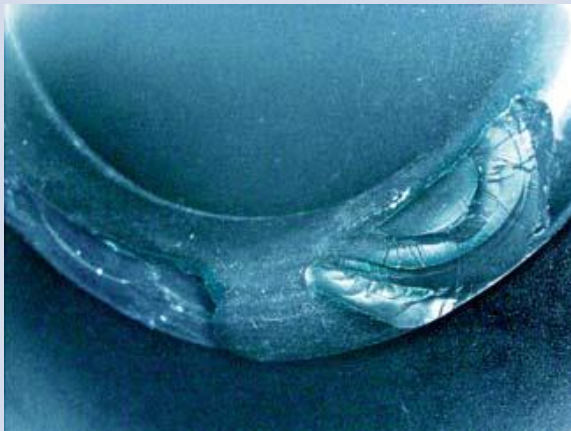
- Accelerated degradation of polymer and change of the surface
- Extraction of ingredients by which the bulk properties will change.

Which will eventually lead to:

- Contamination of product
- Leakage and cross contamination
- Reduced cleanability due to reduced gasket volume (crevice to housing)

Failure modes

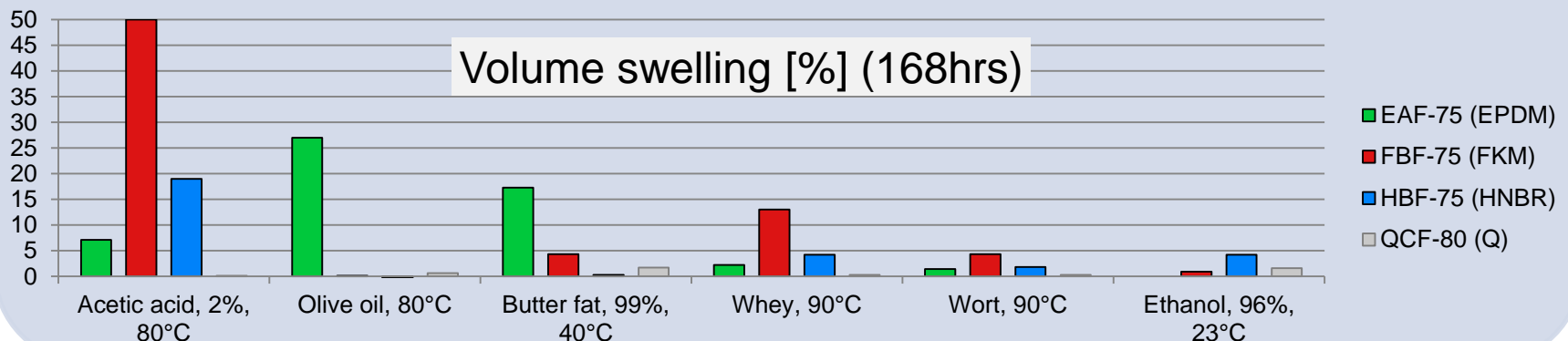
Swelling



Wrong selection of rubber can cause swelling, due to high solubility.
(eg. EPDM and high fat concentration)

Which will eventually lead to:

- Functional error
- Leakage and cross contamination
- Contamination of product due to tear



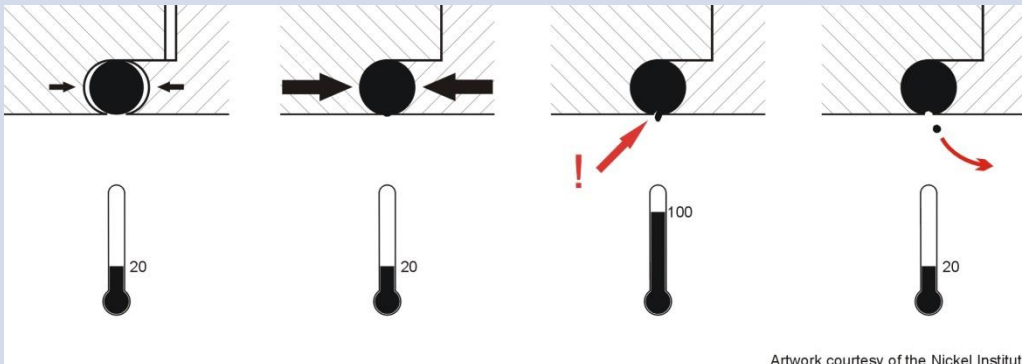
Failure modes

Gap extrusion



Partially related to swelling and temperature increase, but also to pressure dynamics.

- Reduced cleanability
- Risk of gasket debris in product
- Leakage and cross contamination



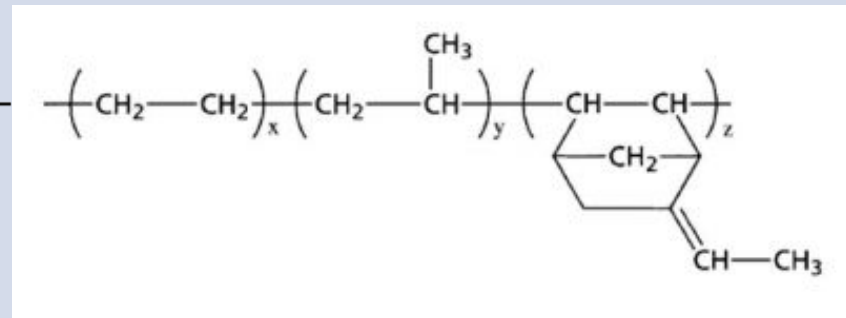
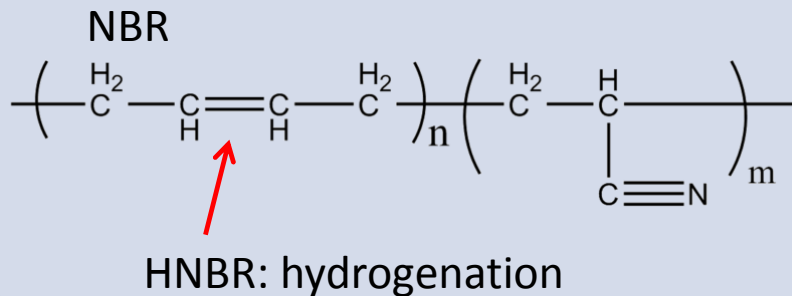
Failure modes

Ozonolysis and oxidation



Polymer scission causing brittleness, cracking and loss of strength

- Reduced cleanability
- Risk of gasket debris in product
- Leakage and cross contamination



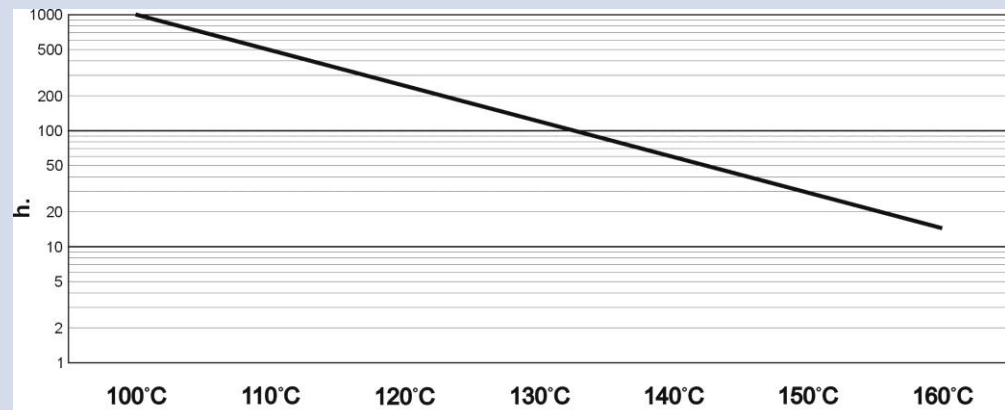
Failure modes

Heat ageing



Polymer degradation and loss of functional ingredients causing brittleness, loss of strength and elongation at break

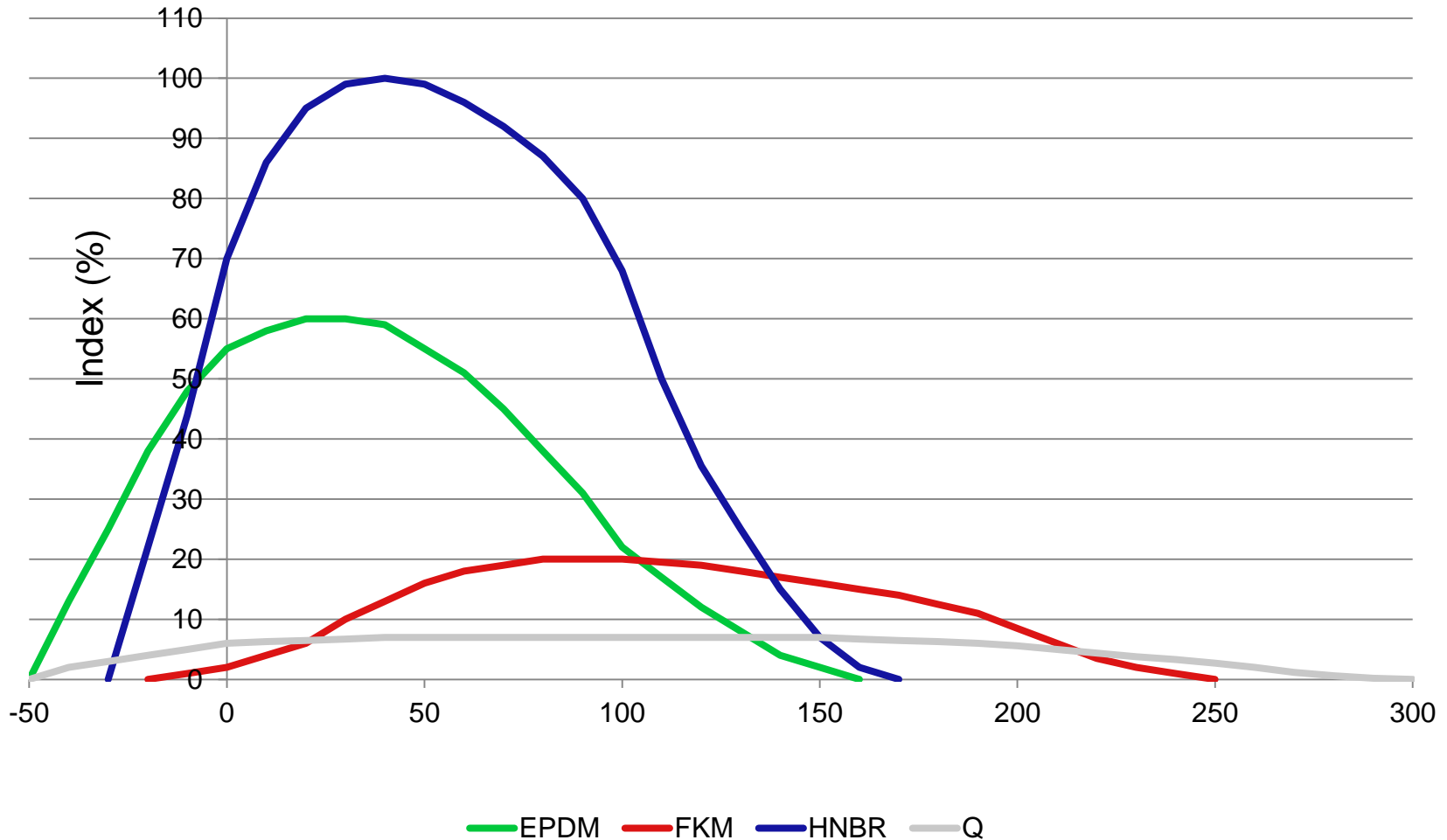
- Tear -> Gasket debris in product
- Loss of volume -> Leakage
- Loss of elasticity -> Leakage



Artwork courtesy of the Nickel Institute

Arbitrary lifetime

as function of temperature
Indexed to HNBR



Failure modes

Overcompression



Result of overcompression
(35%, 120°C, 16 hrs)

Crushing due to local overstressing of material

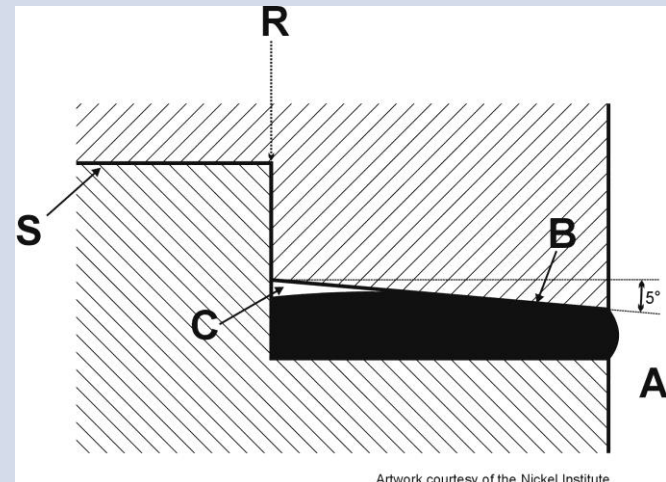
- Reduced cleanability
- Risk of gasket debris in product
- Leakage and cross contamination

A = Product.

B = Gasket.

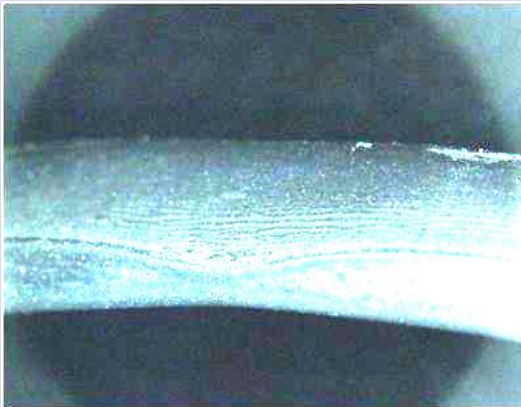
C = Expansion cavity. R = Radial alignment

S = Metal stop to control compression.



Failure modes

High friction

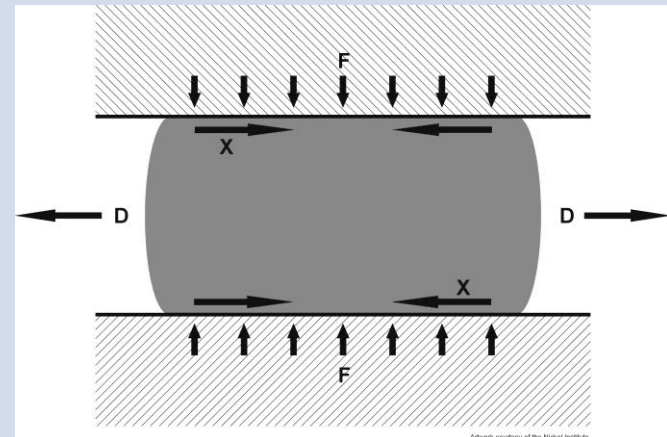


Damage of surface

- Reduced cleanability
- Risk of gasket debris in product
- Leakage and cross contamination

F = Force compressing the seal.
D = Attempted expansion.
X = Frictional forces

Frictional forces may exceed the shear resistance of the elastomer seal and cause surface damage



Explosive decompression



Sudden pressure drop can cause deep cracks in the gasket, as gas is trying to escape:

- Leakage and cross contamination
- Reduced cleanability
- Risk of gasket debris in product

Compounding considerations

EPDM recipe	High quality	Low cost
Pure, well structured EPDM	100	
Low-quality EPDM		100
Carbon black, high purity	80	
Carbon black, low purity		100
Other fillers, e.g. chalk		90
Medical grade mineral oil	10	
Technical grade mineral oil		80
Sulphur + Accelerators		4
Organic peroxide + Activator	4	
Loading	194	374
Hardness	70 ShA	70 ShA
Tensile strength	14 MPa	9 MPa
Compression set, 70 °C, 24 hrs	10%	20%
Swelling in water, 70 °C, 168 hrs	± 2%	± 10%
Taste & smell	None	Noticeable

Target profile for compounding



Considerations

- Compliance: Which applications and markets are to be covered?
- Mechanical properties: Dynamic or static? Load? Flexing?
- Chemical resistance: Product, CIP and SIP to be covered?
- Thermal conditions: Min/Max and continued temperature?
- Expected lifetime and failure criteria?

Qualification

Supplier qualification

- Verification of traceability
- Verification of Good Manufacturing Practice

Part qualification

- Part Submission Warrant
- Process capability documentation

Compound qualification

- Verification of compound compliance
- Technical datasheet
- Material safety data sheet
- Test report against a material specification

EHEDG Guideline No. 48: Elastomeric Seals

- Design principles
- Behaviour of elastomers used for seals
- Hardware design
- Trouble shooting
- Handling of seals
- Legislation
- Technical information provided by suppliers

Acknowledgement



**Thank you to my colleagues at EHEDG subgroup
“Design of Elastomeric Seals”
for making this presentation possible!**

Alfa Laval, Armaturenwerk Hötensleben, CETIM, Dockweiler, Endress&Hauser, Freudenberg, GEA, Hygienic Design, KHS, Kiesel, Klüber Lubrication, Neumo, Nickel Institute, RS, SPX, Pentair Südmo, Timperley Consulting, Trelleborg,