# Innovation and training days : **Materials and Approvals**

19 ET 20 SEPTEMBRE 2019

Techné GROUPE

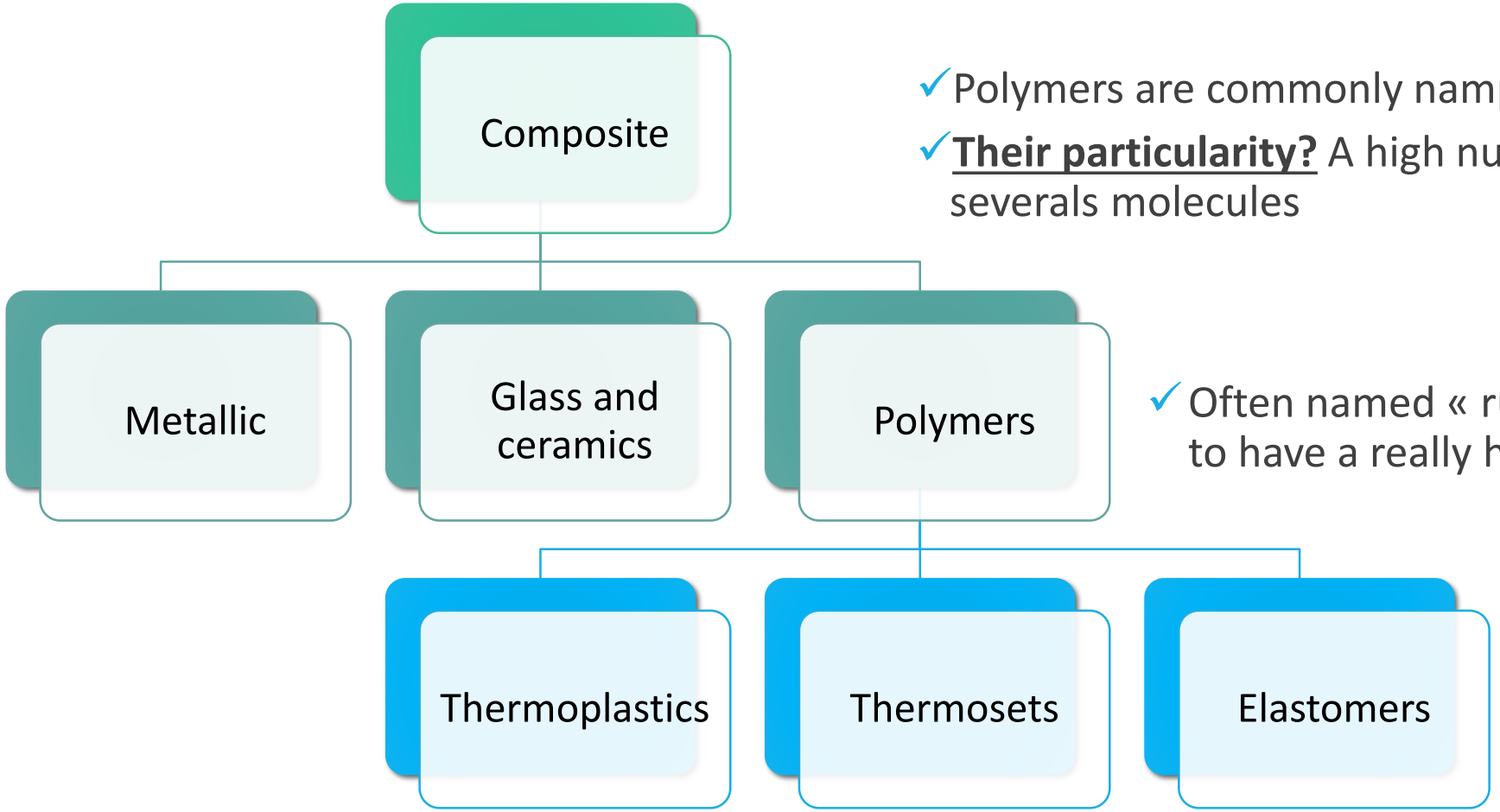
# Summary

I. • What is an elastomer?

II. • How elastomer parts are made?

III. • Which approval(s) for which application(s)?

# What is an elastomer?

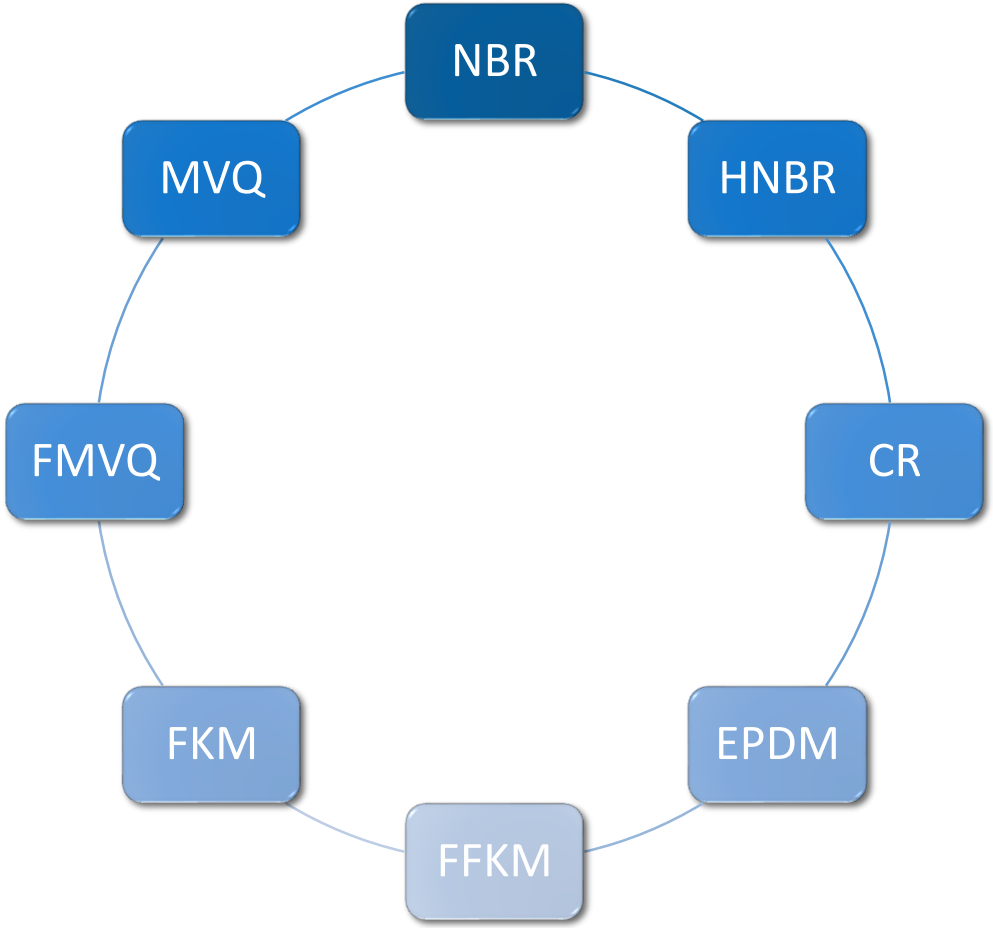



- ✓Polymers are commonly namped « plastics »
- ✓**Their particularity?** A high number of repetitions of one or severals molecules

- ✓Often named « rubbers », elastomers specificity is to have a really high elasticity

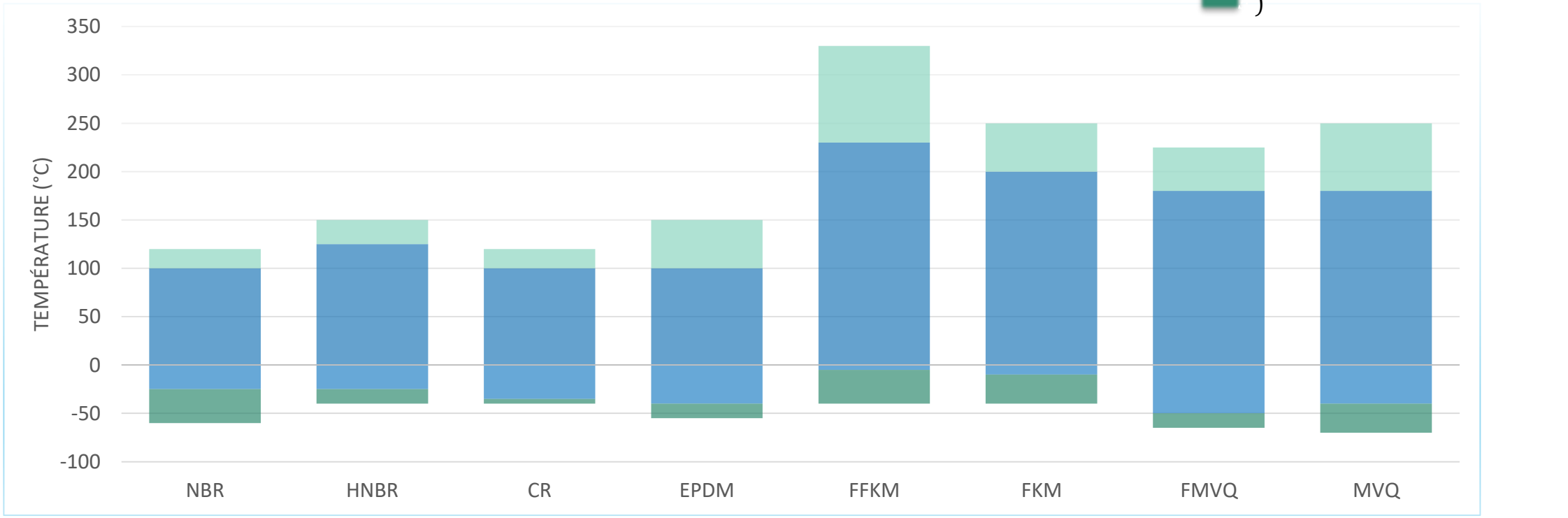
# What is an elastomer?

- Elastomers themselves can be divided in different families
- Every family has its own basic properties
- TECHNE proposes 8 important elastomer families



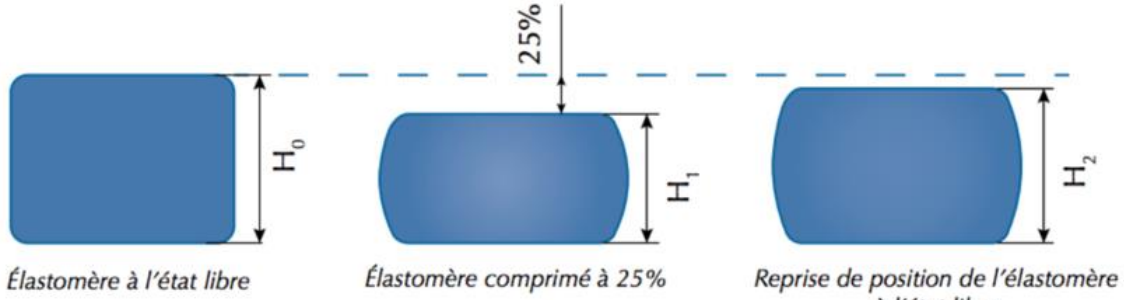
# What is an elastomer?

- Operating temperature range of the different elastomers



# What is an elastomer?

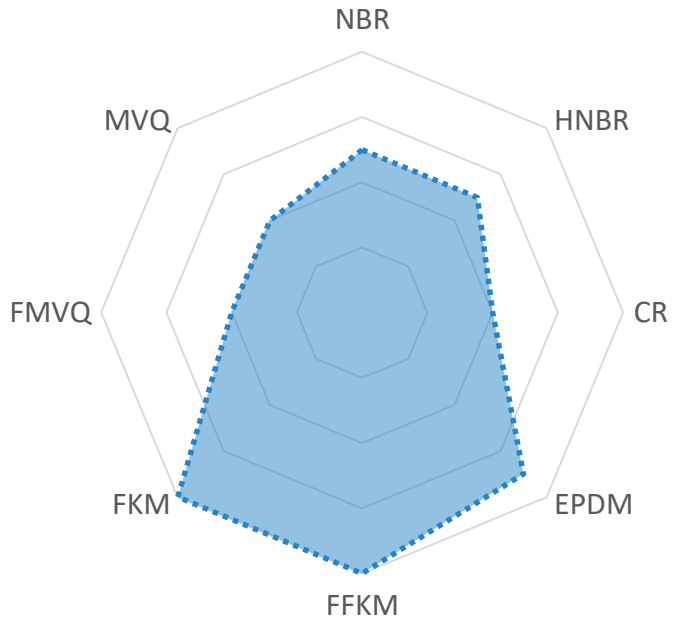
- In sealing fields, the CS (Compression set) is one of the main properties to consider
- CS represents the material elasticity




$$CS\ (\%) = \frac{H_0 - H_1}{H_0 - H_2}$$

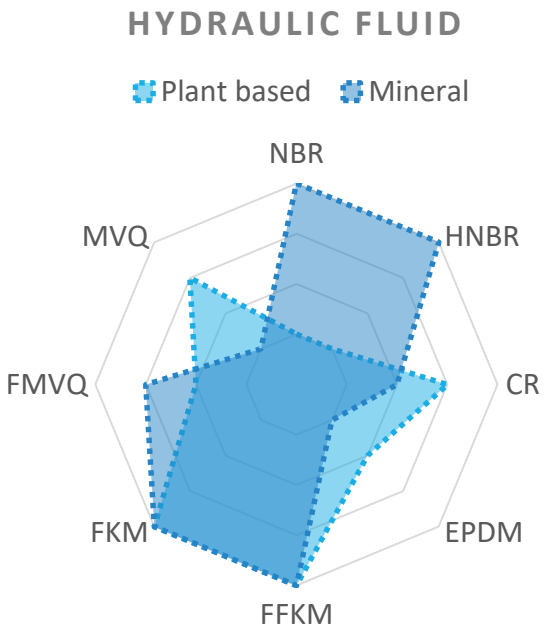
- The lower is the Compression Set, the better is the material elasticity

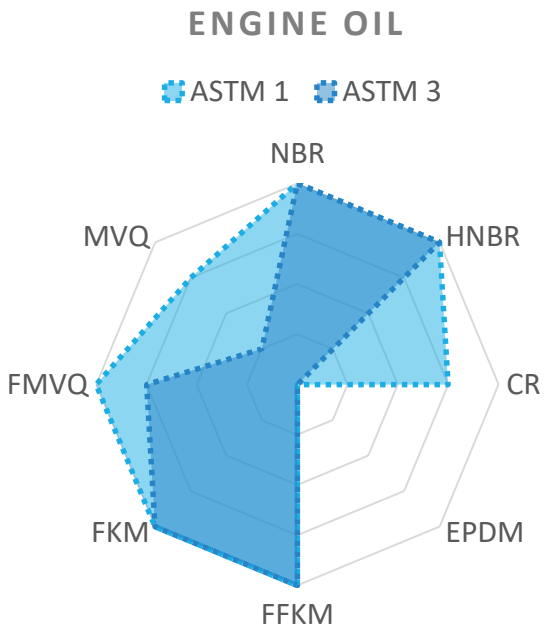
- Compression Set comparison according to the elastomer nature

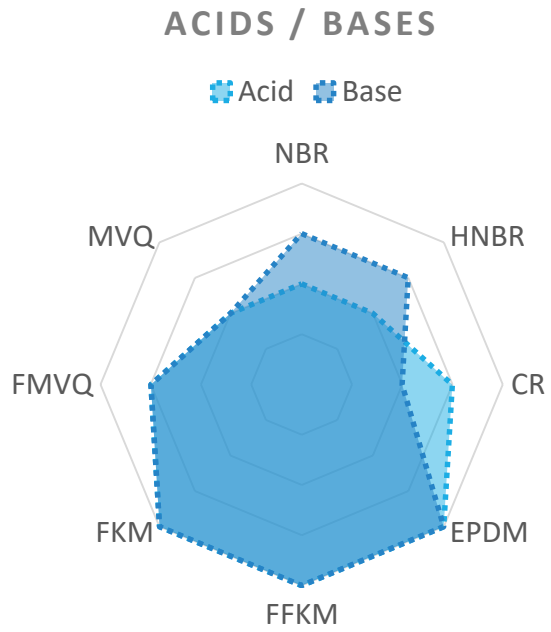


# What is an elastomer?

- Chemical compatibility is widely linked to the elastomer nature



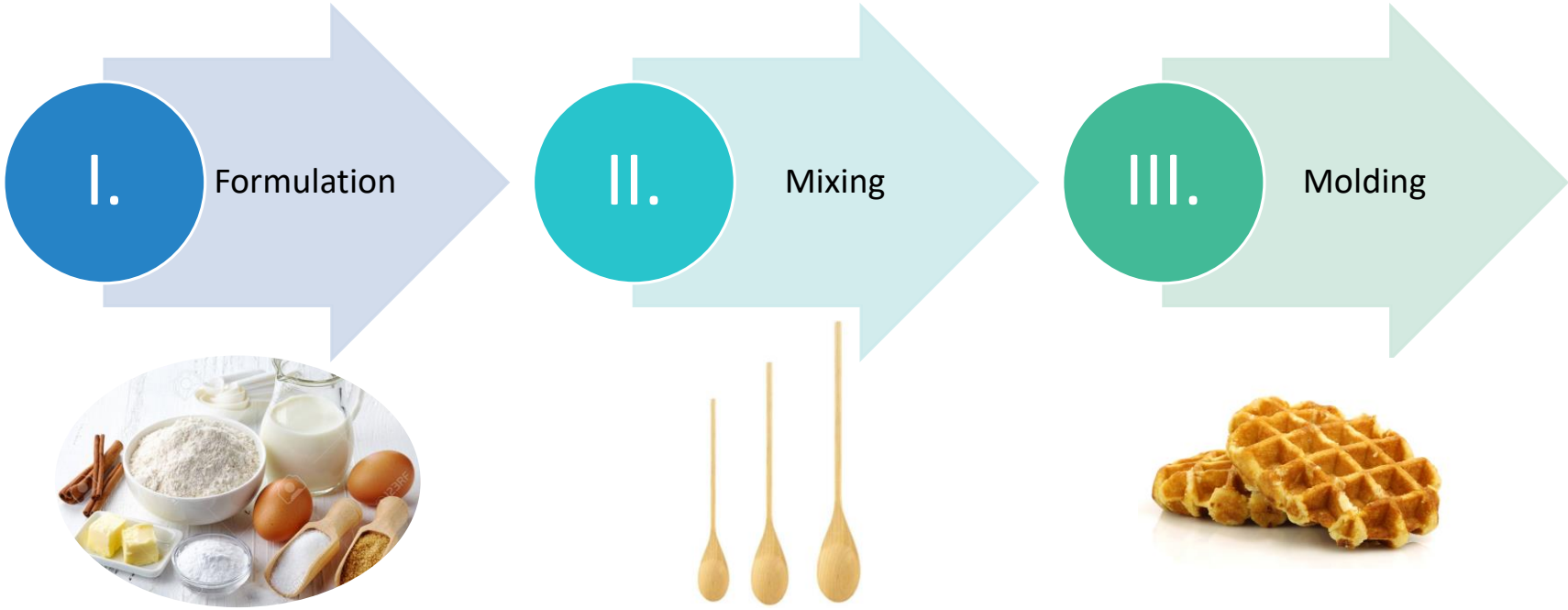




- *These compatibilities are given as an indication*

# How elastomer parts are made?

- What are the necessary steps to produce elastomer parts?




- Every step has a non-negligible influence on parts finals properties

# How elastomer parts are made?

## Formulation

- Every elastomer family owns basic chemicals and physicals properties (chemical resistance, operating temperature range, mechanical properties…)
- Some properties can be improve with a formulation modification
- Most elastomers are formulated as follow :
  - Elastomer basis
  - Plasticizer
  - Filler (Carbon black or silica)
  - Accelerator
  - Catalyst
- It is possible to adjust the components quantity and the nature
- All developments are done in conformity with the requested regulations

# How elastomer parts are made?

**Mixing**

- Once the formulation as been defined, the components need to be mix in order to produce masterbatch

- Mixing involves following an accurate process :
  - Components incorporation order needs to be strictly follow
  - Mixing temperature needs to be control
  - Mixer speed is adjust as function of the introduced components

- Masterbatch is generally in the form of slabs or strip

Components are find in different phases :

Liquid : Plasticizer

Powder : Filler, Accelerator, Catalyst

Solid: Elastomer basis (in the form of bar or roundish)

# How elastomer parts are made?

**Molding**

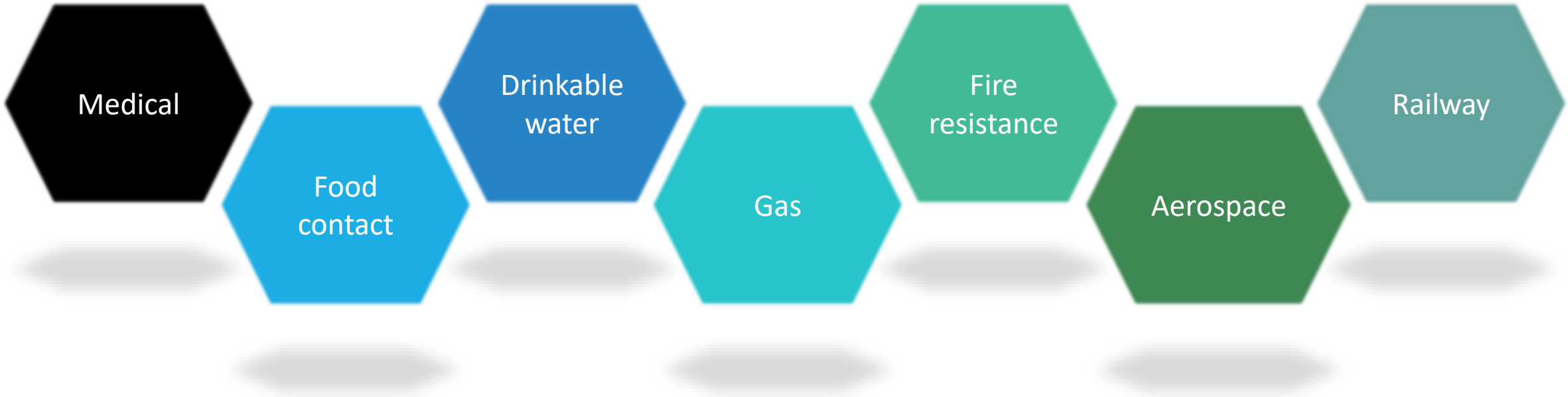
- Different parameters have an important impact on parts physical and geomatrical properties:
  - Pressure
  - Temperature
  - Curing time
  - Post curing

- Parts final dimensions are defined by the choice of the mold
- Shrinkage is specific to each material, it explains why a mold can only be used with one material

**The combination of these steps enable to create custom-made parts, as function of the expressed needs**

# Which approval(s) for which application(s)?

- For some applications certifications are necessary




- Techné certifies materials, not final parts

# Approved materials :


## Medical

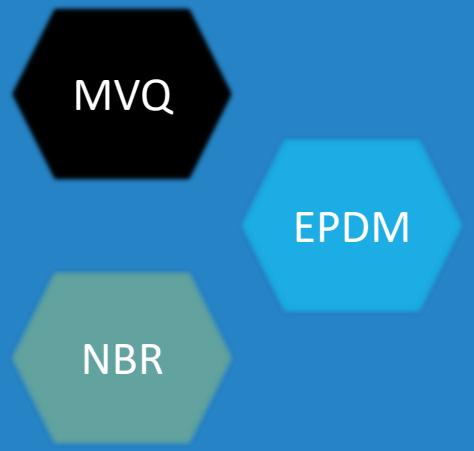
- The reference approval in medical and pharmaceutical field is USP VI (US Pharmacopeia) class VI
- Materials can be approved according to 2 chapters
  - Chapter <87> Tests in vitro
  - Chapter <88> Tests in vivo
- **Possible applications :**
  - Syringe piston seal
  - Equipment for sleep apnoea
  - Medical fluid plumbing

# Approved materials :


## Food contact

- Europe
  - Harmonize with regulation **CE 1935/2004**
  - Migration test in different simulant
- USA
  - **FDA** regulation has 2 different levels:
  - FDA Positive list = Self-certification according to a list of authorized components
  - FDA Migration tests = Performance of test in different simulant
- China
  - Since 2016, China established its own certification **GB 4806.11**
  - Certification in 2 steps
    I. Conformity to positive list
    II. Migration test
- **Possible application :**
  - Plumbing in contact with alimentary fluids

# Approved materials :




## Drinkable water

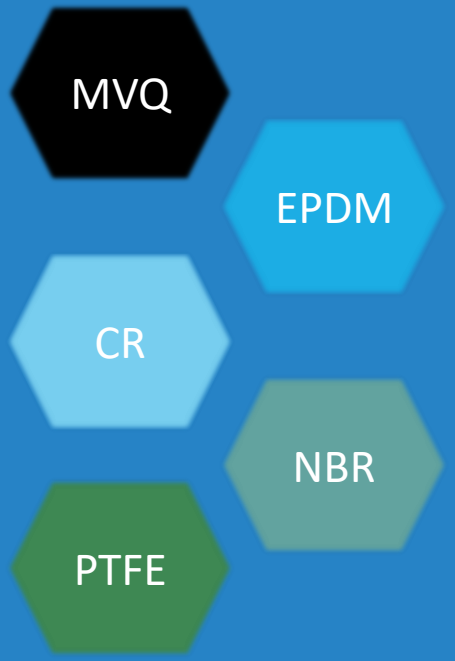
- France
  - CLP (List positive conformity) adequate for parts with inner diameter below 63mm
  - ACS (Attestation de Conformité Sanitaire) requires migration test
- Germany
  - UBA (UmweltBundesAmt) Positive list + migration test
  - Previously named KTW
  - W270 is a migration and bacteria development test
- England
  - WRAS (Water Regulations Advisory Scheme) Migration and organoleptic tests
- **Applications possibles:**
  - Water meter
  - Sanitary plumbing

# Approved materials :


## Gas

- EN 549
  - European standard for gas contact products
  - Classification by hardness and temperature
  - Ageing in 3 fluids
  - Renewal every year
- EN 682
  - European standard for pipelines and connectors for gas and liquid hydrocarbon transportation
  - Ageing tests with gas and/or hydrocarbon
  - Choice of a temperature range test
- **Applications possibles:**
  - Gas pressure regulation
  - Pipelines

# Approved materials :




## Fire resistance

- UL 94
  - Elastomer classification according to the flamability degree
    - HB: tests in vertical position
    - V2 V1 V0: tests in vertical position, V0 being the highest level of fire resistance

- **Possible applications:**
  - Electronic material (computer, speaker…)
  - Fire material (detector, alarm box…)

# Approved materials :


## Aerospace

- NFL 17-107
  - Tests according to specifications every 3 years in laboratory
    - Hardness, density, compression set
    - Mechanical properties
    - Ageing in aeronautical fluids
  - Mechanical tests for each batch production

- **Application possible:**
  - Landing gear flexible seals

# Approved materials :

EPDM

## Railway

- EN 45 545
  - European standard to manage « smoke and fire » in trains
  - Is is structured according to :
    - Type of vahicule (HL1, HL2 et HL3)
    - The part final use Rx (In total 26 application types are defined)

- **Applications possibles:**
  - Train engine
  - Light housing seals

# Materials & approvals

- ✓ More than 2 500 materials proposed
- ✓ 1 000 approvals
  - FDA Positive list : 450
  - UL94 : 30
  - 1935/2004 : 40
  - WRAS : 70
  - CLP : 40
- ✓ And much more approvals:
  - 3A
  - BNIC
  - Norsok M710…

- ✓ Multi-Approvals materials
  - ✓ All in One : Water – Food – Medical
    - 1935/2004
    - FDA
    - ACS
    - UBA
    - WRAS
    - 3A
    - USP VI