

# Transposing technical guides of the Council of Europe in Belgian and Benelux legislation

Els Heyvaert – DGAPF – Service Food, Feed and Other Consumption Products



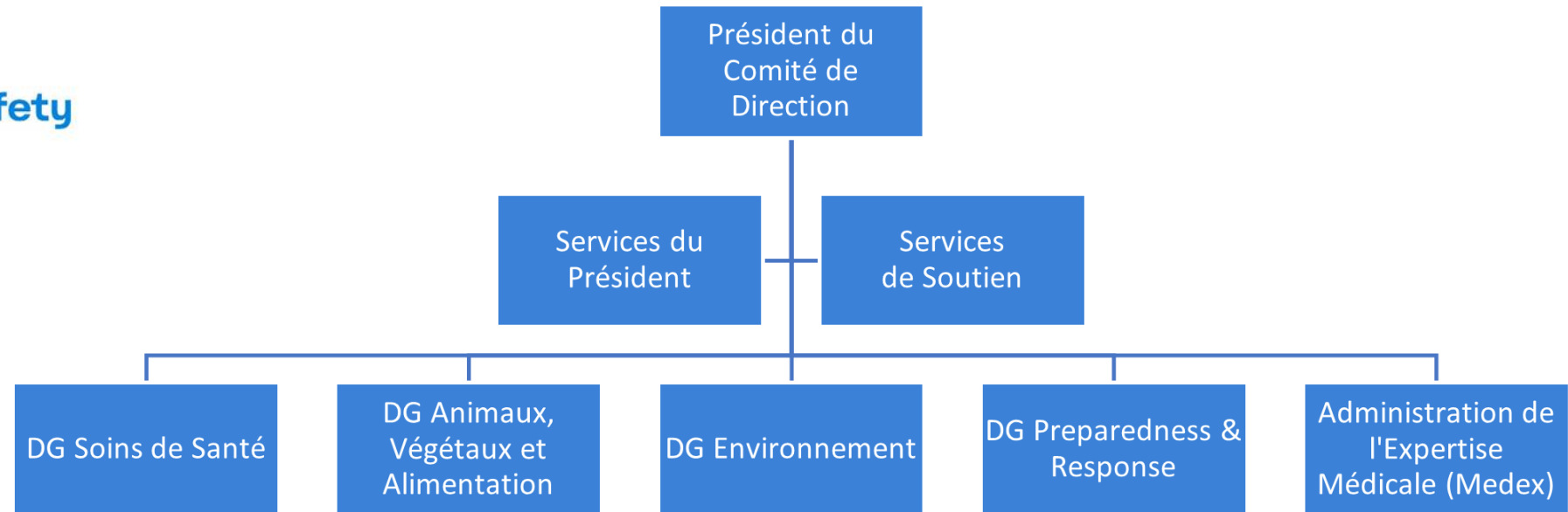
Health  
Food Chain Safety  
Environment

Service Public Fédéral Santé publique, Sécurité de la Chaîne alimentaire et Environnement

Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu



**Health  
Food Chain Safety  
Environment**



**Website of the FPS Health**  
[www.health.fgov.be](http://www.health.fgov.be)



*Chemical Contaminants*  
*Microbiological Contaminants*  
*Allergs*  
*Labeling*  
*Claims*  
*Food Contact Materials*  
*Novel Food*  
*Infant/Follow-on formula*  
*Baby Food*  
*FSMP*  
*Water*  
*Bottled water*  
*Additifs*  
*flavourings*  
*Enzymes*  
*processing aids*



Evidence-based Policy  
Food risk management  
Regulation (Food Standard)  
Guidances  
Risk communication  
Stakeholders relations and consultation  
Pre-marketing authorisations and notifications  
for food  
Commissioning and funding scientific studies

# FCM legislation in Belgium

Framework Regulation  
Regulation 1935/2004

Good Manufacturing Practices  
Regulation 2023/2006

Declaration of Compliance  
RD 11/5/1992

European Legislation

Plastic  
Reg. 10/2011

Active and Intelligent  
Materials  
Reg. 450/2009

Recycled Plastic  
Reg. 2022/1616

Regenerated Cellulose  
Dir. 2007/42/EC  
RD 23/11/2004

Ceramics  
Dir. 84/200/EC  
RD 1/5/2006

Specific Substances

Nitrosamines  
Dir. 93/11/EEG

BPA  
Reg. 2018/213

BADGE/NODGE/BFDGE  
Reg. 1895/2005

National Legislation

Glas  
RD 11/5/1992

Paper and board  
RD 11/5/1992

Metals and Alloys  
RD 17/2/2021

Coatings and Varnishes  
RD 25/9/2016

BPA 0 – 3 years  
Law 4/9/2011

Council of Europe

(Soft law)  
Resolutions and Technical  
Documents  
Cork  
Paper and Board  
Ion exchange resins,  
Silicones,  
...

Benelux

Metals and Alloys  
decision M (2022) 12

# Council of Europe

# Resolutions and guidelines

## Free publications from EDQM

- Resolution CM/Res(2020)9/ Safety and quality of FCM
  - Technical Guide Paper and board (2021)
- Resolution(2013): Metals and alloys
- Resolution AP(89)1: Colorants for plastics
- Resolution AP(92)2: Polymerisation aids
- Resolution AP(2004)1: Coatings
- Resolution AP(2004)2: Cork
- Resolution AP(2004)3: Ion exchange resins
- Resolution AP(2004)4: Rubber
- Resolution AP(2004)5: Silicons
- Resolution AP(2005)2: Inks
- Guidelines (2004): Glass

Total or partial transposition in the national law to become binding.

In absence of specific EU or national Regulations → reference to show the harmlessness and the inertia of a FCM (art. 3 of the Reg (EU) 1935/2004)

# Resolutions and guidelines

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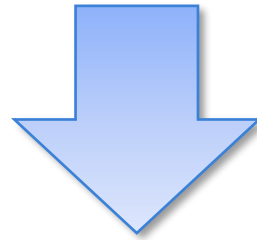
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# Varnishes and Coatings

Resolution AP(2004) on coatings  
intended to come into contact with  
foodstuffs



Belgian Royal Decree 25/09/2016  
concerning varnishes and coatings  
intended to come into contact with  
foodstuffs

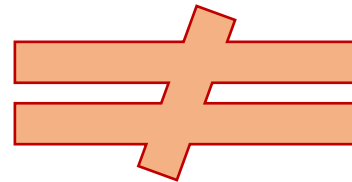
## Scope + definition



- Apply to varnishes which, in the finished state, are intended to come into contact with food and are designed for that purpose.
- The following types of varnishes are covered:
  - Varnish for metal materials and articles;
  - Varnish for flexible materials and articles;
  - High performance varnishes.

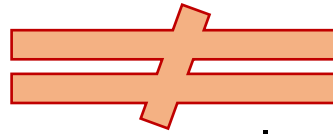
## DoC

- New in RD



Additives, monomers and other starting substances can be used in the manufacture of varnishes, if they are:

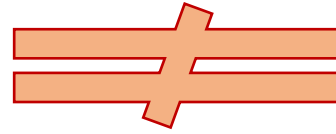
## CoE



## Belgium

- Substances in positive list for coatings (see Tech. Doc. 1)
    - List A: monomers and other starting substances assessed by SCF/EFSA
    - List B: monomers approved by MS's (of former Partial Agreement) or by the FDA, applying the criteria at the time of their approval
    - List C: additives assessed by SCF/EFSA
    - List D: additives approved by MS's (of former Partial Agreement) or by the FDA, applying the criteria at the time of their approval
  - Aids to Polymerisation (AP's) for plastics in ResAP(92)2
- Included in European Regulation No. 10/2011,
    - applying the same restrictions/specifications
    - except when the use in specific plastics is stated
  - Approved by a EU Member State
    - applying the more stringent restrictions/specifications
  - Positively evaluated by EFSA, or scientific institutes with equivalent competences
  - An evaluation carried out by the *Belgian Superior Health Council*

## CoE



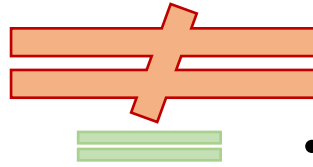
## Belgium

- They comply with Art.3 of EU Reg. 1935/2004
- They do not transfer their constituents to foodstuffs in quantities exceeding 10 µg/kg of food or simulant
- They are not classified as CMR according to the criteria laid down EU Reg. 1272/2008 and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures (+ nano)
- They are not genotoxic based on QSAR predictions, in case of absence of in vitro and in vivo toxicological data following EFSA's criteria
- The principle of non-migration (i.e. LOD < 10 µg/kg) is applied

## Overall Migration Limit (OML) + testing conditions

### CoE

- OML = 10 mg/dm<sup>2</sup>, or
- OML 60 mg/kg food if:
  - containers of 500ml – 10l
  - articles which can be filled and impracticable to estimate the surface area in contact with foodstuffs;
  - caps, gaskets, stoppers or other similar devices for sealing.



### Belgium

- OML = 10 mg/dm<sup>2</sup>, or
- OML 60 mg/kg food if:
  - Intended for infants and young children (Reg (EU) 609/2013)
- Coatings on metals are excluded

### Overall migration testing:

- High performance varnishes: 3% acetic acid
  - 3% Acetic acid is used for the migration, but only the chloroform soluble organic material is weighed and compared to the overall migration limit

# Testing conditions Specific Migration Limit (SML) + Simulants

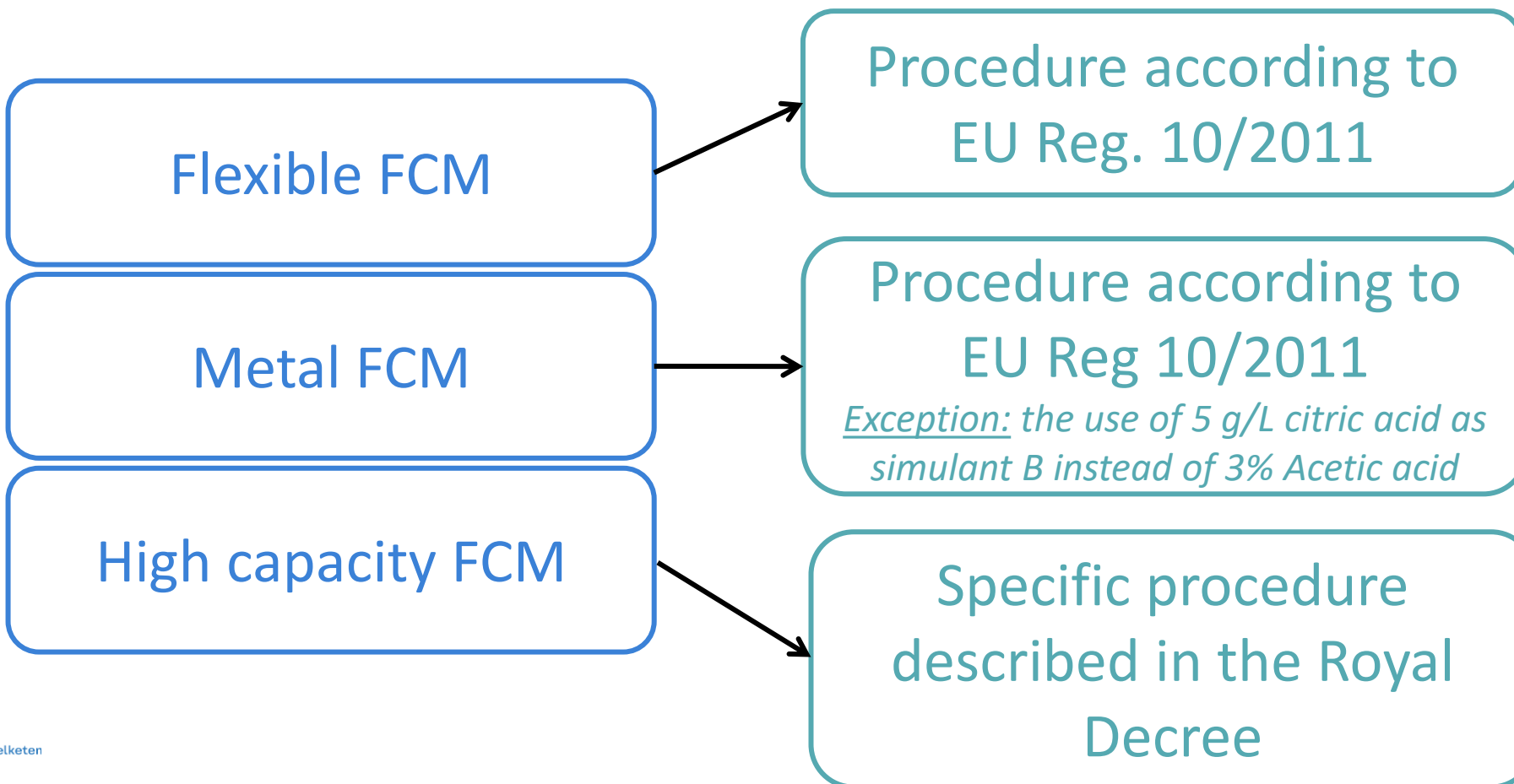
## CoE



## Belgium

- No specific instruction or simulants
  - Refereces to simulants in positive lists

- Specific instructions + simulants



# Metals and Alloys



Resolution CM/Res(2013)9 on Metals and alloys used in food contact materials and articles



Belgian Royal Decree 17/02/2021 on metals and alloys in materials and articles intended to come into contact with foodstuffs




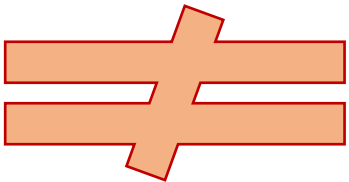
Benelux decision M (2022) 12 on metals and alloys in materials and articles intended to come into contact with foodstuffs

Resolution CM/Res(2013)9 on Metals and alloys used  
in food contact materials and articles



Belgian Royal Decree 17/02/2021 on metals and alloys  
in materials and articles intended to come into contact  
with foodstuffs

- 
- Scope + definitions
  - DoC
  - Specific Release Limits
  - Testing methods + calculations → guidelines RD



- Reference to hygiene legislation (EU Legislation)
- Reference to ISO standards
- Labelling (also in 1935/2004)
- Riskassessments (Chapter 2)

Tableau 1 : LLS applicables aux métaux et aux composants d'alliages

Symbole	Nom	LLS (mg/kg aliment)
Al	Aluminium	5
Sb	Antimoine	0,04
Ag	Argent	0,08
Cr	Chrome	0,250
Co	Cobalt	0,02
Cu	Cuivre	4
Sn*	Etain	100
Fe	Fer	40
Mg	Magnésium	-
Mn	Manganèse	1,8
Mo	Molybdène	0,12
Ni	Nickel	0,14
Ti	Titane	-
V	Vanadium	0,01
Zn	Zinc	5

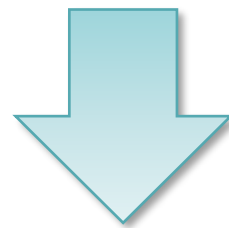


\* Sauf dans le Champs d'application du règlement (CE) n °1881/2006

Tableau 2 : LLS applicables aux métaux sous forme de contaminants et d'impuretés.

Symbole	Nom	LLS (mg/kg aliment)
As	Arsenic	0,002
Ba	Baryum	1,2
Be	Béryllium	0,01
Cd	Cadmium	0,005
Li	Lithium	0,048
Hg	Mercure	0,003
Pb	Plomb	0,010
Tl	Thalium	0,0001

Belgian Royal Decree 17/02/2021 on metals and alloys in materials and articles intended to come into contact with foodstuffs



Benelux decision M (2022) 12 on metals and alloys in materials and articles intended to come into contact with foodstuffs

# Benelux

# BENELUX



**Population**

29.7 million

**7%**

of EU population



**Territory**

70,640 km<sup>2</sup>

**2%**

of EU territory



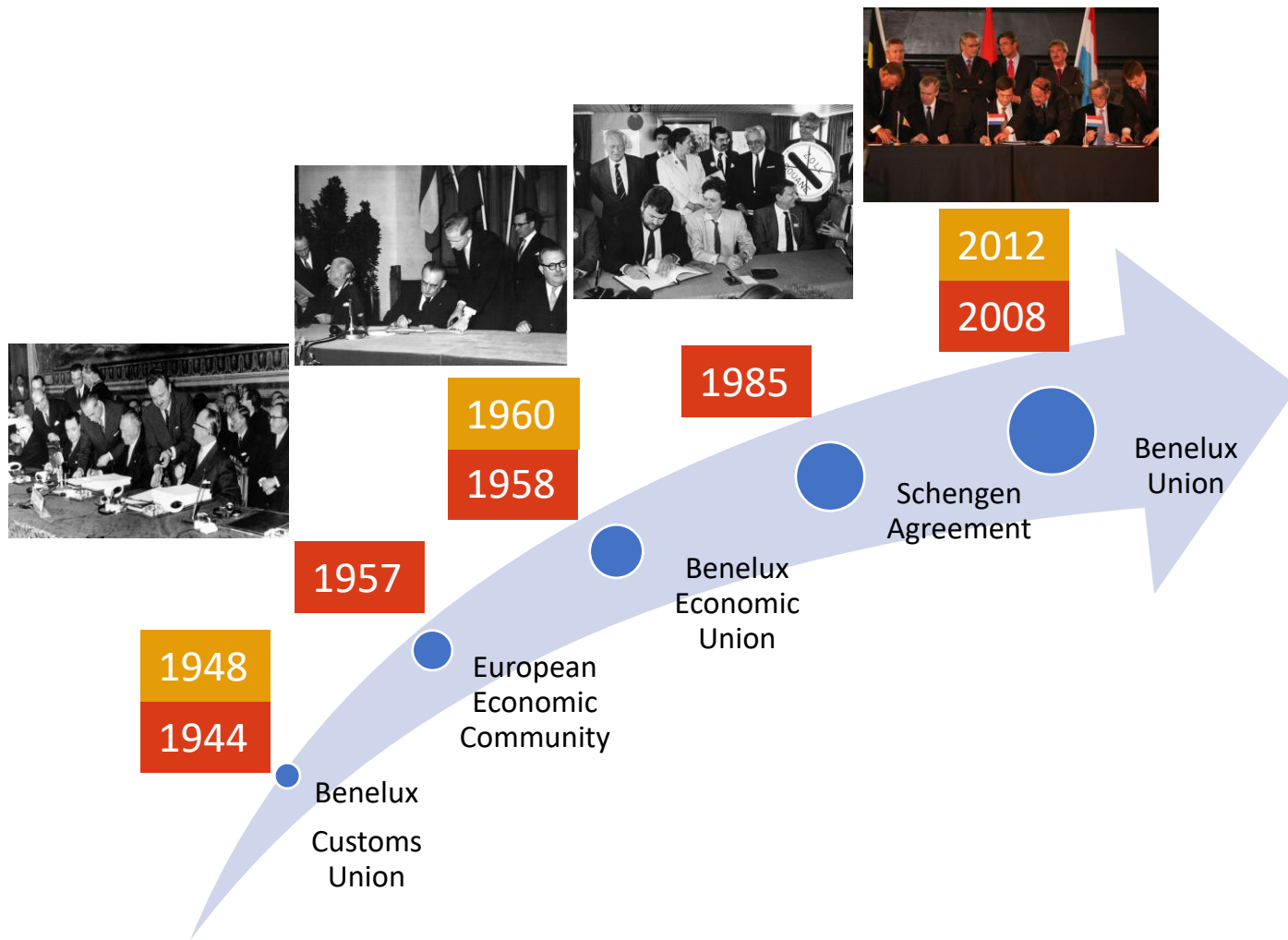
**GDP**

€ 48,238 per capita

**10%**

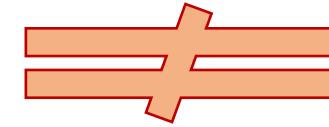
of EU economy

# RETROSPECTIVE





- Different wording but same meaning
- Special labelling indications
  - Benelux countries may require a manufacturer to affix special labelling indications or a symbol describing the conditions of use to be respected for the materials and articles.
- The Netherlands and Grand Duchy of Luxembourg are transposing the decision into national law
- New limits (new version resolution) will be transposed in the near future



More information

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[FOD Volksgezondheid \(belgium.be\)](http://belgium.be)