



# Mineral Oils in Food and Food Contact Regulations in the EU

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# Agenda

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- Overview of the rules applicable to MO in:
  - Food contact (FC) legislation
  - Food additive (FA) legislation
  - Pesticides legislation
- General considerations for comparison

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# Mineral oils in Food contact legislation

# Food contact materials

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- Framework Regulation = general provisions and principles for FCM
- Intended to ensure:
  - the effective functioning of the internal market in relation to the placing on the market in the EU of materials and articles intended to come into contact directly or indirectly with food
  - whilst providing the basis for **securing a high level of protection of human health and the interests of consumers**

# Food contact materials

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- Evaluation of substances to be listed are done by the EFSA based on petitions submitted by interested parties on the basis of supporting data re mainly:
  - the chemical properties and intended application of a substance
  - Exposure of the substance by means of migration in food or residual content of the substance in the food contact material
  - the toxicological profile of the substance



## FCM Substance No 93

- Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks
- SML of 0.05 mg/kg food
- Restrictions: Not to be used for articles in contact with fatty foods for which simulant D assigned
- Specifications:
  - Hydrocarbons with  $<C_{25} \Rightarrow \leq 40$  % w/w
  - Viscosity at 100 °C  $\geq 2.5$  cSt ( $2.5 \times 10^{-6}$  m<sup>2</sup>/s)
  - Average molecular weight  $\geq 350$  Da ( $\approx C_{25}$ )



## FCM Substance No 94

- Waxes, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks
- No SML is specified → Generic SML of 60 mg/kg food applies
- Specifications:
  - Hydrocarbons with  $<C_{25} \Rightarrow \leq 5\%$  (w/w)
  - Viscosity at  $100^{\circ}C \geq 11\text{cSt}$  ( $11 \times 10^{-6} \text{m}^2/\text{s}$ )
  - Average molecular weight  $\geq 500 \text{ Da}$  ( $\approx C_{36}$ )



## FCM Substance No 95

- White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks
- No SML specified → Generic SML of 60 mg/kg food applies
- Specifications:
  - Hydrocarbons with  $<C_{25} \Rightarrow \leq 5\%$  (w/w)
  - Viscosity at  $100^{\circ}C \geq 8.5cSt$  ( $8.5 \times 10^{-6}m^2/s$ )
  - Average molecular weight  $\geq 480 Da$  ( $\approx C_{34}$ )



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# Member States Specific Food Contact Legislation



# The Netherlands

## -- Regulations of 20 Nov 1979



### Hydrocarbons C10-C14

- Listed in Appendix A, chapter 1, section 2.4 (aids to polymerization and PPA for plastic food contact materials)
- Specifications: Aromatic content should be  $\leq 1\%$
- Restriction: None

# The Netherlands

## -- Regulations of 20 Nov 1979



### Liquid paraffin

- Listed in chapters II (paper), IV (metals), VII (textiles), IX (wood and cork) and X (coatings)
- Specifications:
  - Color weaker than standard Saybolt 30
  - Odor must be almost absent
  - Re. presence of (poly)aromatics
- Restriction: none

# The Netherlands

## -- Regulations of 20 Nov 1979



**Paraffin, microcrystalline wax:** Listed in chapters II (paper) , III (rubber) and X (coatings)

- Specifications re presence of (poly)aromatics
- Restriction: None

**Paraffin, solid including synthetic:** Listed in chapters II (paper), III (rubber), IV (metals), VII (textiles), IX (wood and cork) and X (coatings)

- Specifications re presence of (poly)aromatics
- Restriction: None

# The Netherlands

## -- Regulations of 20 Nov 1979



### Aliphatic hydrocarbons

- Chapter X (coatings)
- Specification: boiling point up to 160°C (covers up to  $\approx$  C9)
- Restriction: none

### Aromatic hydrocarbons

- Chapter X (coatings)
- Specification: boiling point up to 180°C excluding benzene (covers up to  $\approx$  C10)
- Restriction: none

# Spain

## -- Decree 847/2011

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### Synthetic paraffin

### Hydrocarbon wax, paraffinic and microcrystalline

- Additives
- Specification: none
- Restriction: SML = 0.01 mg/kg

Any substance listed in another EU MS can be used



- Applies to aids to polymerization and PPAs in polymeric materials
  - Polyethylene wax
  - Cycloalkanes  
Restriction: 0-100°C (we understand this is the boiling point of cycloalkanes, which are up to C6-7)
  - Liquid paraffins (including refined mineral oil)
  - Microcrystalline paraffins
  - Solid paraffins (including synthetic paraffins)

No restrictions and no specifications for any of these substances mentioned



- BfR Recommendation XXXVI on paper and board for food contact
  - VI. Defoamers:
    - 7. Liquid paraffins, max. 0.1 % (for purity requirements see 155th Communication)
- The BfR has established for MOSH with carbon chain lengths of C10 to C16 a guidance value of 12 mg/kg food





- **Mineral paraffinic oil and paraffinic wax, including microcrystalline wax**
  - Specification: food quality
  - Restriction: SML 0.3 mg/kg or for hydrogenated oil/wax: SML 3 mg/kg
- **Polyethylene wax**
  - Specification: none
  - Restriction: none



### Dispersions of waxes, paraffins and polyolefins

- Annex IV (paper and board)
- Specification: none
- Restriction: maximum use level of 2% of the finished product

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# Mineral oils in Food legislation

# Food additives

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- **Regulation 1333/2008 on food additives** lays down rules on additives used in foods with a view to
  - ensuring the effective functioning of the internal market
  - whilst ensuring a **high level of protection of human health and a high level of consumer protection**
  - including the protection of consumer interests and fair practices in food trade
  - **taking into account, where appropriate, the protection of the environment**

# Food additives

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- Positive lists system set by Regulation 1333/2008
- Safety assessments carried by EFSA, based on petitions containing data re chemistry and specifications of petitioned substances, intended uses, toxicological studies and known and anticipated exposure
- Purity specifications set in Regulation 231/2012

# Regulation 1333/2008

## -- Listings of interest

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- **Microcrystalline wax - E 905**

- Authorized for use in the surface treatment of confectionery (excluding chocolate), chewing gum and melons, papaya, mango and avocado
- *At quantum satis*

- **Purity specs (Regulation 231/2012)**

- Molecular weight : average not less than 500
- Viscosity:  $\geq 1.1 \times 10^{-5} \text{ m}^2\text{s}^{-1}$  at 100°C  
Alternative:  $\geq 0.8 \times 10^{-5} \text{ m}^2\text{s}^{-1}$  at 120°C, if solid at 100 °C
- Carbon number at 5% distillation point:  $\leq 5\%$  of molecules < C25
- Polycyclic aromatic compounds: Benzo(a)pyrene no more than 50 µg/kg

# Regulation 1333/2008

## -- Listings of interest

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- **Hydrogenated poly-1-decene - E 907**

- Authorized for use as glazing agent only on certain foods, e.g. dried fruits, sugar confectionery, chewing gum, decorations
- Up to 2000 mg/kg

- **Purity specs (Regulation 231/2012)**

- Molecular weight : 560 (average)
- Assay:  $\geq 98.5$  % of hydrogenated poly-1-decene, having the following oligomer distribution: C<sub>30</sub>: 13-37%; C<sub>40</sub>: 35-70%; C<sub>50</sub>: 9-25%, and C<sub>60</sub>: 1-7%
- Viscosity: between  $5.7 \times 10^{-6}$  and  $6.1 \times 10^{-6}$  m<sup>2</sup>s<sup>-1</sup> at 100°C
- Compounds with < C30:  $\leq 1.5$ %

# Food processing aids

## -- Order of 19 October 2006



- France = only EU Member State with positive list
- Paraffin oil: release agent
  - Spaghetti and pasta soup. Use level: quantum satis; Maximum residual dose: 20 mg/kg food
  - Fine bakery and cheese; Use level: quantum satis; Maximum residual dose: dose technically unavoidable
- Mineral oil with high molecular weight: release agent
  - *Tuiles*
  - Use level: quantum satis; Mineral oil must be used in a mixture with beeswax
  - Residual content for mineral oil: less than 2 g/kg; Technically inevitable dose for beeswax



# Food processing aids

-- Order of 19 October 2006



- Mineral oil may be used until 31/12/2014
  - As a release agent for confectionery
  - As an antifoam agent for crystallized white sugar

=> Maximum residual level: Dose technically unavoidable

# Food processing aids

## -- Order of 19 October 2006



- Relevant specifications for mineral oils used as food processing aids:
  - **Low molecular weight mineral oil**
    - Viscosity at 100°C 3.5-8.5 cSt
    - Boiling point 300-400°C = 5% distillation (<C25)
    - Average molecular weight : 350 – 480 Da
    - Testing on PAHs
  - **High molecular weight mineral oil**
    - Viscosity at 100°C 8.5-11 cSt
    - Boiling point 400 - 430°C = 5% distillation (>=C25)
    - Average molecular weight :480-510 Da
    - Testing on PAHs

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# Mineral oils in EU legislation on plant protection products

# Plant protection products

## -- Regulation 1107/2009

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- Active substances must be approved at EU level, following assessment by EFSA
- Data should be submitted on:
  - the identity of an active substance and plant protection product
  - the physical and chemical properties
  - the effects on target pests
  - the risks to workers, consumers, environment and non-target plants and animals

# Regulations 540/2011 & 396/2005

## -- Listings of interest and limits

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- **Paraffin oils**

- CAS Reg. No 64742-46-7 (C11 – C25)
- CAS Reg. No 72623-86-0 (C15 – C30)
- CAS Reg. No 8042-47-5 (C18 - C30)
- CAS Reg. No 97862-82-3 (C11 – C30)

- Approval: 1 January 2010

- Expiration: 31 December 2019

- Purity requirements: it is referred to in the European Pharmacopoeia 6.0

- Limits: Max residue level: 0.01 mg/kg (default limit set in Regulation 396/2005)

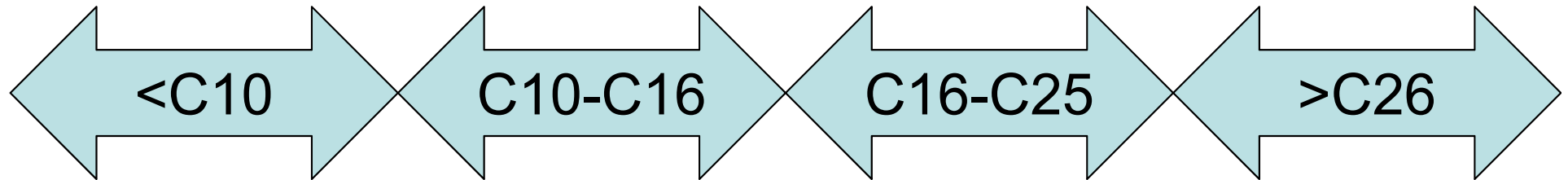
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# General Considerations re Comparison


# Overall


	Food contact legislation	Food additive legislation	Pesticide legislation
Dossiers evaluated by:	EFSA	EFSA	EFSA
Data included in dossier:			
Chemical properties and intended application	Yes	Yes	Yes
Exposure to food	Yes	Yes	Yes
Toxicological properties	Yes	Yes	Yes
Effects on workers, the environment and non-target plants and animals	No	workers/animals: No Environment: where appropriate	Yes


# Limits for substances with a specific carbon size fraction





 Aliphatic hydrocarbons up to  $\approx$  C9  
Restriction: boiling point  $\leq$  160°C

 Aromatic hydrocarbons  
Restriction: boiling point  $\leq$  180°C


 Cycloalkanes up to  $\approx$  C7  
Restriction: boiling point  $\leq$  100°C

 Hydrocarbons C10-C14  
Restriction: aromatic content  $\leq$  1%

 MOSH C10-C16  
SML = 12 mg/kg

 Paraffinic oil C11-C25  
MRL = 0.01 mg/kg








None

 Paraffinic oil C15-C30  
MRL = 0.01 mg/kg

None



# Substances without carbon size fractions, with limits

- Paraffinic wax/microcrystalline wax and mineral oil
  - Non-hydrogenated: 0.3 mg/kg 
  - Hydrogenated: 3 mg/kg 
- Liquid paraffin
  - Non-hydrogenated: 18 mg/kg  (18g paper/6dm<sup>2</sup> x 6 dm<sup>2</sup>/kg x 0.1%)
- Synthetic paraffin
  - 0.01 mg/kg 
- Hydrocarbon wax, paraffinic and microcrystalline
  - 0.01 mg/kg 
- Paraffinic oil 
  - 20 mg/kg
- Mineral oil (high molecular weight)
  - 2 g/mg 

# Maximum amount for certain carbon size fraction in substance

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- **Paraffinic hydrocarbons <C25**
  - 40% of 0.05 mg/kg = 0.02 mg/kg (FCM Sub No. 93)
  - 5% of 60 mg/kg = 3 mg/kg (FCM Sub Nos. 94 and 95)
  - 5% of *Quantum satis* = >>> mg/kg (E 905)
- **Paraffinic hydrocarbons <C30**
  - 1.5% of 2000 mg/kg = 30 mg/kg (E 907)

# Conclusions

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- The different legislations (on food, FCM and pesticides) are made taking into account different considerations
- The names used in different (and sometimes within the same) sets of legislation are not consistent
- Mainly all limits are set only for fraction <C16
- Most limits set in the FC and FA legislation are for MOSH only
- Generic restrictions exist for MOSH without size restriction, but they address the (poly)aromatics present in the hydrocarbon substance



# Thank you!

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