Mineral Oils in Food and Food Contact Regulations in the EU

MOCRINIS WORKSHOP, 10-11 September 2013

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Agenda

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

- General considerations for comparison
Mineral oils in Food contact legislation
Food contact materials

- 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

- Evaluation of substances to be listed are done by the EFSA based on petitions submitted by interested parties on the basis of supporting data are 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
Plastics Regulation

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 \(<\text{C}_{25}\) \(\leq 40\%\ w/w\)
  - Viscosity at 100 °C \(\geq 2.5\text{cSt} (2.5\times10^{-6}\text{ m}^2/\text{s})\)
  - Average molecular weight \(\geq 350\text{ Da} (\approx \text{C}_{25})\)
Plastics Regulation

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 \(<\text{C25} \Rightarrow \leq 5\% \text{ (w/w)}\)
  - Viscosity at 100°C \(\geq 11\text{cSt} \left(11 \times 10^{-6}\text{m}^2/\text{s}\right)\)
  - Average molecular weight \(\geq 500\ \text{Da} \left(\approx \text{C36}\right)\)
Plastics Regulation

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 <C25 => ≤5 % (w/w)
- Viscosity at 100°C ≥8.5cSt (8.5×10⁻⁶m²/s)
- Average molecular weight ≥480 Da (≈C34)
Member States
Specific Food
Contact Legislation
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
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
Aliphatic hydrocarbons

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

Aromatic hydrocarbons

- Chapter X (coatings)
- Specification: boiling point up to 180°C excluding benzene (covers up to ≈ C10)
- Restriction: none
Spain
-- Decree 847/2011

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
Spain
-- Resolution 1982

- 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
Germany
– BfR Recommendations

- 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
France
-- Order of 9 Nov 1994 on Rubber

- 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
Belgium
-- Order of 11 May 1992

Dispersions of waxes, paraffins and polyolefins

- Annex IV (paper and board)
- Specification: none
- Restriction: maximum use level of 2% of the finished product
Mineral oils in Food legislation
Food additives

- **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

- 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
**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: $\geq 1.1 \times 10^{-5}$ m$^2$s$^{-1}$ at 100°C
  - Alternative: $\geq 0.8 \times 10^{-5}$ m$^2$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

- **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: ≥98.5 % of hydrogenated poly-1-decene, having the following oligomer distribution: C\(_{30}\): 13-37%; C\(_{40}\): 35-70%; C\(_{50}\): 9-25%, and C\(_{60}\): 1-7%
  - Viscosity: between 5.7×10\(^{-6}\) and 6.1×10\(^{-6}\) m\(^2\)s\(^{-1}\) at 100°C
  - Compounds with < C30: ≤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 backery 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
Mineral oils in EU legislation on plant protection products
Plant protection products
-- Regulation 1107/2009

- 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

- **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)
General Considerations re Comparison
### Overall

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Limits for substances with a specific carbon size fraction

- **<C10**
  - Aliphatic hydrocarbons up to ≈ C9
  - Restriction: boiling point ≤ 160°C
- **C10-C16**
  - Hydrocarbons C10-C14
    - Restriction: aromatic content ≤ 1%
- **C16-C25**
  - None
- **>C26**
  - None

**Aromatic hydrocarbons**
- Restriction: boiling point ≤ 180°C

**Cycloalkanes**
- up to ≈ C7
- Restriction: boiling point ≤ 100°C

**Paraffinic oil**
- C11-C25
- MRL = 0.01 mg/kg

**MOSH**
- C10-C16
- SML = 12 mg/kg

**Paraffinic oil**
- C15-C30
- MRL = 0.01 mg/kg
### 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/6dm² x 6 dm²/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

- **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

- 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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