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ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

MOCRINIS II

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(Shell, MOCRINIS Chairman)

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MOCRINIS the joint effort forward

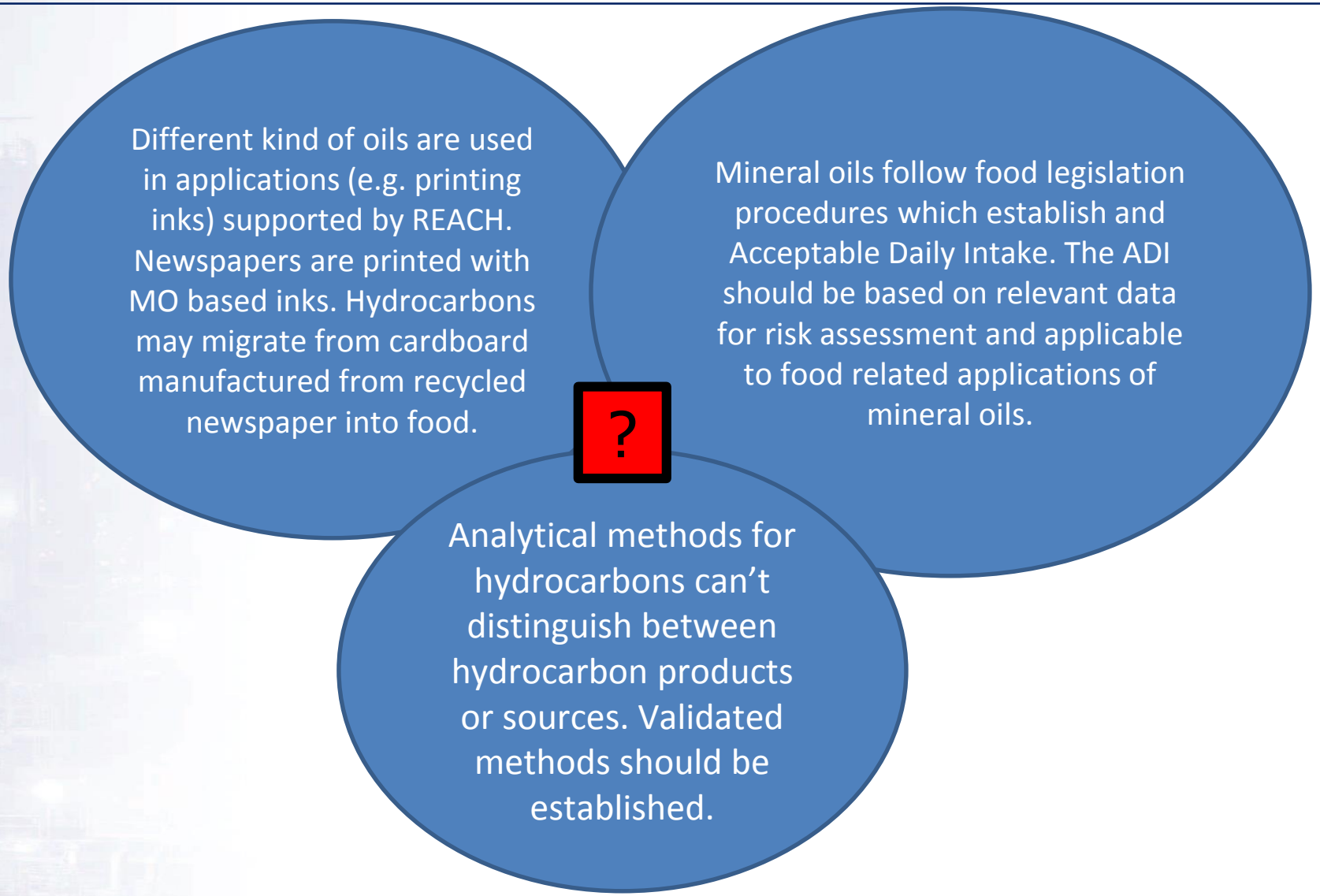
Why MOCRINIS?

- Mineral Oil:
  - is it an issue of Mineral Oil or hydrocarbons in general?
  - Is it about products or fractions of hydrocarbons?
- Cross Industry:
  - Is not only about printing inks anymore
  - Hydrocarbon complex substances are used in different downstream industries regulated by different legislations
- Issues:
  - Not easily resolved due to the complex nature of the substances
  - Overlapping hydrocarbon ranges of complex substances (and background hydrocarbons)
  - Toxicological interpretation of available studies
  - Differences in analytical procedures to ensure compliance
  - What are the practical approaches suggested?

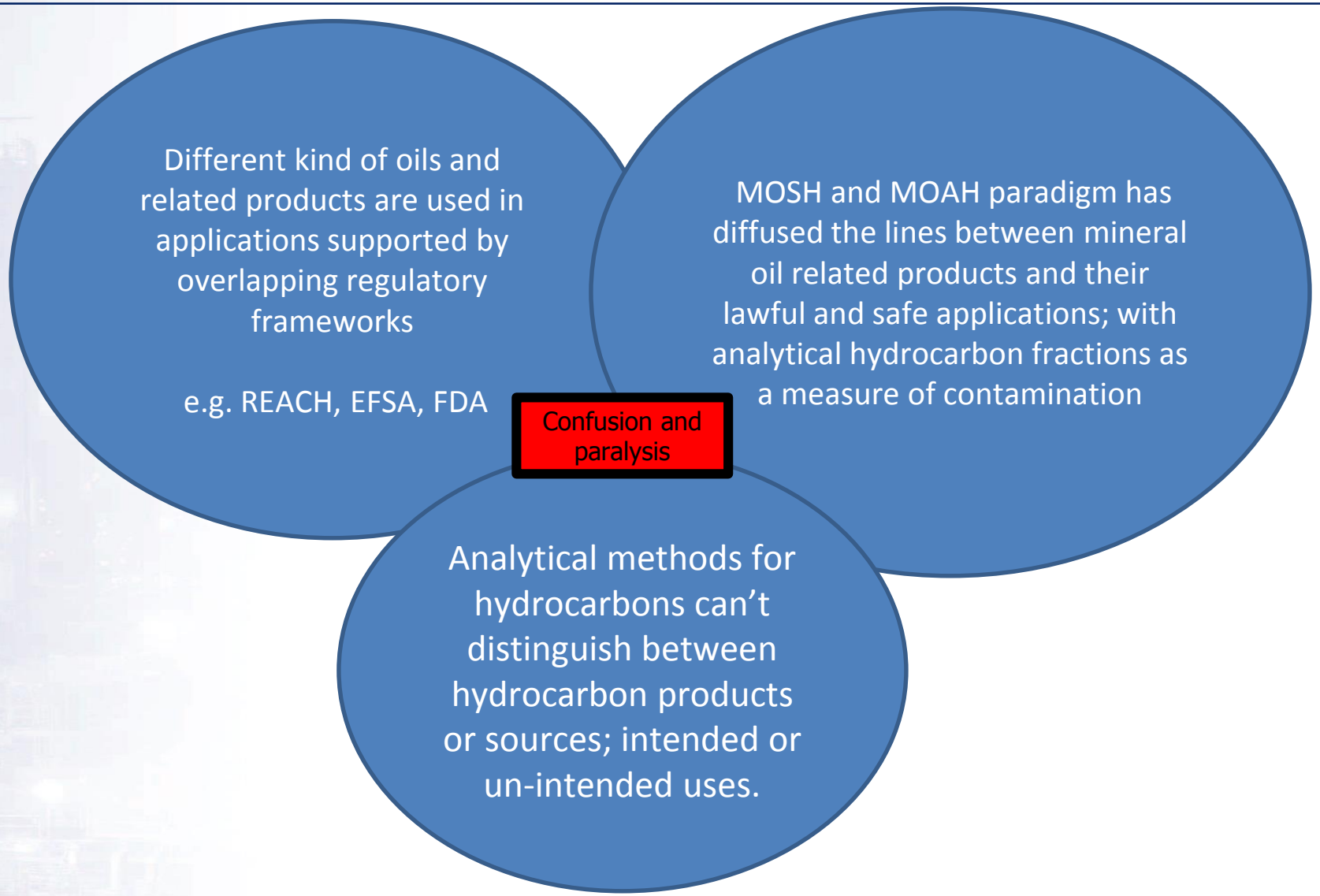
Purpose of MOCRINIS II

- Follow up of MOCRINIS I
- Facilitate a discussion forum with stakeholders
- Present CONCAWE point of view
- Have a constructive discussion and listen to others
- Gain clarity on the issues
- Hazard and risk assessment based on science
- Appropriate regulatory approach
- Review EFSA's recommendations and 2017 studies on mineral oils and waxes
- Present CONCAWE and EWF action plan

MOCRINIS I overlapping issues

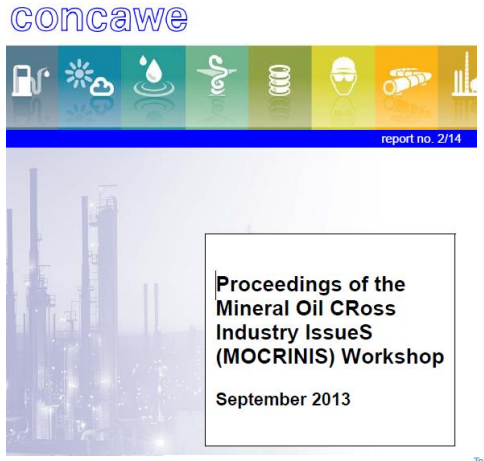


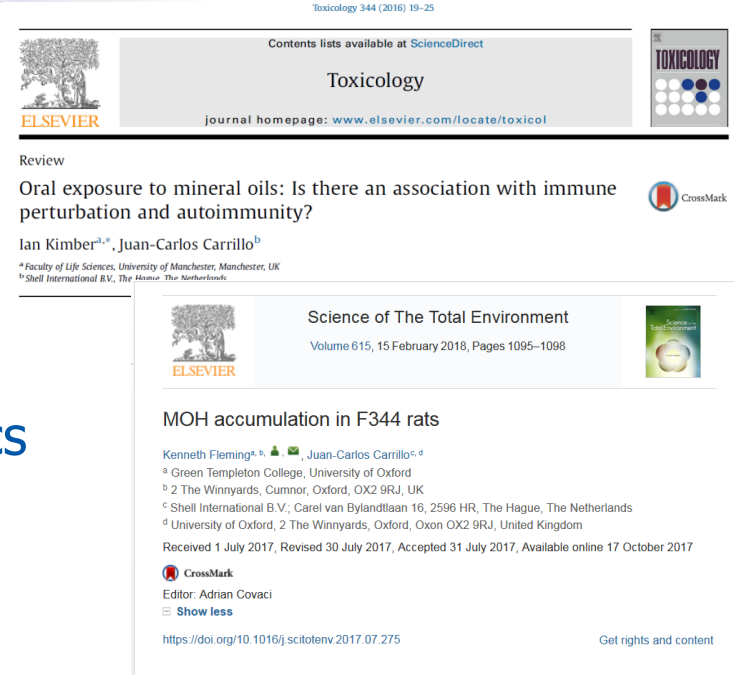
MOCRINIS II overlapping issues



MOCRINIS I Follow-up

- What has happened since MOCRINIS I – Sep.2013
  - MOCRINIS I report published
  - MOCRINIS stakeholder forum
    - Platform to engage with industry sectors on MO issues
    - Exchange of information
    - Joint projects (e.g. Tennant data base)
- New CONCAWE task force, STF-33 was set up in 2015
  - CONCAWE and EWF member companies
  - Prioritize issues related to CONCAWE and EWF products
  - Autoimmunity effect of MO
  - Understanding of MOAH
  - Support the use of Pharmacopeia grade products in cosmetics
  - Exposure data base project
  - Technical specification dossier project





Mineral Oil – What is it?

- Generic term used to group several petroleum derived liquids with "oil-like" viscosity
- Manufactured by vacuum distillation of the residue from atmospheric distillation.
- ~ 40 substances (identifiers or CAS number) which could be regarded as "mineral oil" with boiling points from 300^{0}C to 700^{0}C.
- Differ in physical chemical properties (e.g. viscosity) and chemical composition (e.g. aromatic content).
- Because of thousands of isomers, MO can't be described with a single chemical formula.
- Mineral oils are described as *complex substances* of ***U**nknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials*, or shortly **UVCB.**
- Mineral oil is matrix, a single entity, with its own intrinsic properties behaving as a (complex) substance.
  - hydrocarbon constituents follow a physical chemical pattern
  - varying according to crude oil
  - controlled manufacture,

- In the EU, by law "mineral oils" are UVCBs and not mixtures.
- A mixture are intentionally blended to achieve a certain composition.
- Mineral oil is a substance

- Hydrocarbon solvents have a different manufacturing process which distinguishes them from mineral oil, with their chain lengths up to C20.
- Because of this the MOSH-MOAH terminology does not apply to hydrocarbon solvents.

MOSH and MOAH – What is it?

Chromatography context:

Mineral Oil Saturated Hydrocarbons - MOSH:

The "unresolved complex mixture" of aliphatic hydrocarbons between C20 and C35, containing multibranched saturated and alkylated multiple ring naphtenic alkanes; the carbon numbers are defined by the elution range respectively the retention time of the corresponding n-alkanes in a gas chromatographic analysis on a dimethylpolysiloxane coated column.

- MOSH is used as a chromatographic measure of the alkane content of an oil
- The concern around long term toxicity of mineral oil is derived from observations in animal experiments which are extrapolated to the human situation
- These adverse effects have been extrapolated to humans and serve as the basis for the health concern to the MOSH fraction
- MOSH is a fraction, not a substance on the market.

MOSH and MOAH – What is it?

Chromatography context:

Mineral Oil Aromatic Hydrocarbons -MOAH:

(Highly alkylated) aromatic hydrocarbons with carbon numbers between C20 and C35, of one or more aromatic rings; the carbon numbers are defined by the elution range respectively the retention time of the corresponding n-alkanes in a gas chromatographic analysis on a dimethylpolysiloxane coated column.

- MOAH is used as a chromatographic measure of the aromatic content of an oil
- It is considered as an indicator of the presence of unrefined petroleum based products
- The concern is based on the possibility that MOAH fraction containing 3-7 membered rings may be potentially carcinogenic
- MOAH is a fraction, not a substance on the market.

MOSH and MOAH Issue

- MOSH and MOAH are vague terms, their interpretation is highly contextual
- MOSH and MOAH fractions do not correspond to petroleum products that are placed on the market
- These fractions may contain constituents coming from products of different degrees of refining and purity
- Furthermore, these fractions can also be found in products of other origin than mineral oil, for example, n-alkanes of natural origin found in fruits and vegetables
- MOSH and MOAH is contextual: impossibility of tracing their origin and the health risk they pose
  - MOAH can be harmless or of concern deepening on the origin.
- There are petroleum derived products that are lawfully used (e.g. cosmetic and food contact).
  - refined products are safe
  - presence of MOSH and MOAH is expected, unavoidable
  - no reason for suspecting non-compliance or health risk

The MOSH and MOAH "meaning" is subject of ***when***, ***what*** and ***how*** you use it.

Focus of MOCRINIS 2

- Understand how our products are manufactured
- Regulatory overlap according to specifications
- Latest MOSH and MOAH toxicological interpretation
- What are the regulatory consequences due to new toxicological insight
- Way forward

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Thank you