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ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

Understanding petroleum substances from a regulatory perspective

Concawe Symposium

24 February 2015

Glen Carty

Outline

- Petroleum Substances (PS) – challenges for regulatory treatment
- Concawe approach for REACH Registration
- Challenges of REACH Evaluation 2012-2016
- Concawe REACH strategy & plan for 2015-2019

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Petroleum substances – challenges for regulatory treatment

Issue 1: Complexity

PS are UVCBs.

- The number of individual chemical compounds increases rapidly with carbon number.
- For complex PS with thousands of constituents, none exceeds a threshold triggering classification.

The predominant compounds are described by carbon number / boiling point and hydrocarbon type.

- Carbon number / boiling point ranges are influenced by fractionation.
- Hydrocarbon types are influenced by chemical processing.

To correctly and practically consider the hazards, testing is conducted on the substances as manufactured, not the individual constituents.

C number	Boiling point °C (n-alkanes)	Number of isomers (alkanes only!)	
3	-42	1	
4	-1	2	
5	36	3	
6	69	5	
7	98	Gasoline & naphthas	9
8	126		18
10	174		75
15	269	Gas oils	4 347
20	343		366 231
25	402	Heavy products	36 777 419
30	450		4 108 221 447
35	490		493 054 243 760
40	525		62 353 826 654 563

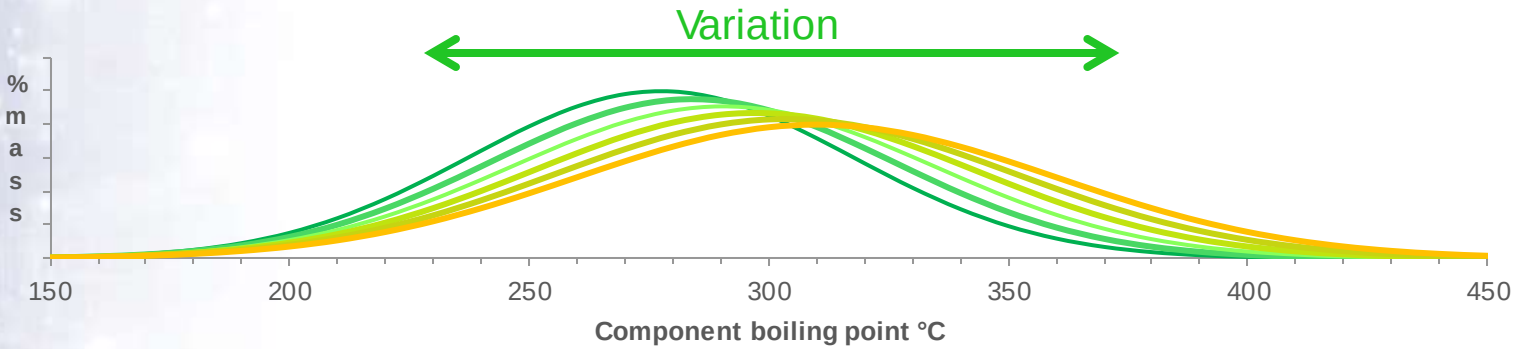
Issue 2: Variability

Stream composition varies continuously over time due to several factors

- Feed quality
- Processing severity
- Separation temperatures, sharpness
- Catalyst / equipment deterioration
- Maintenance cycles

Example

Illustration of effect of varying imperfect fractionation



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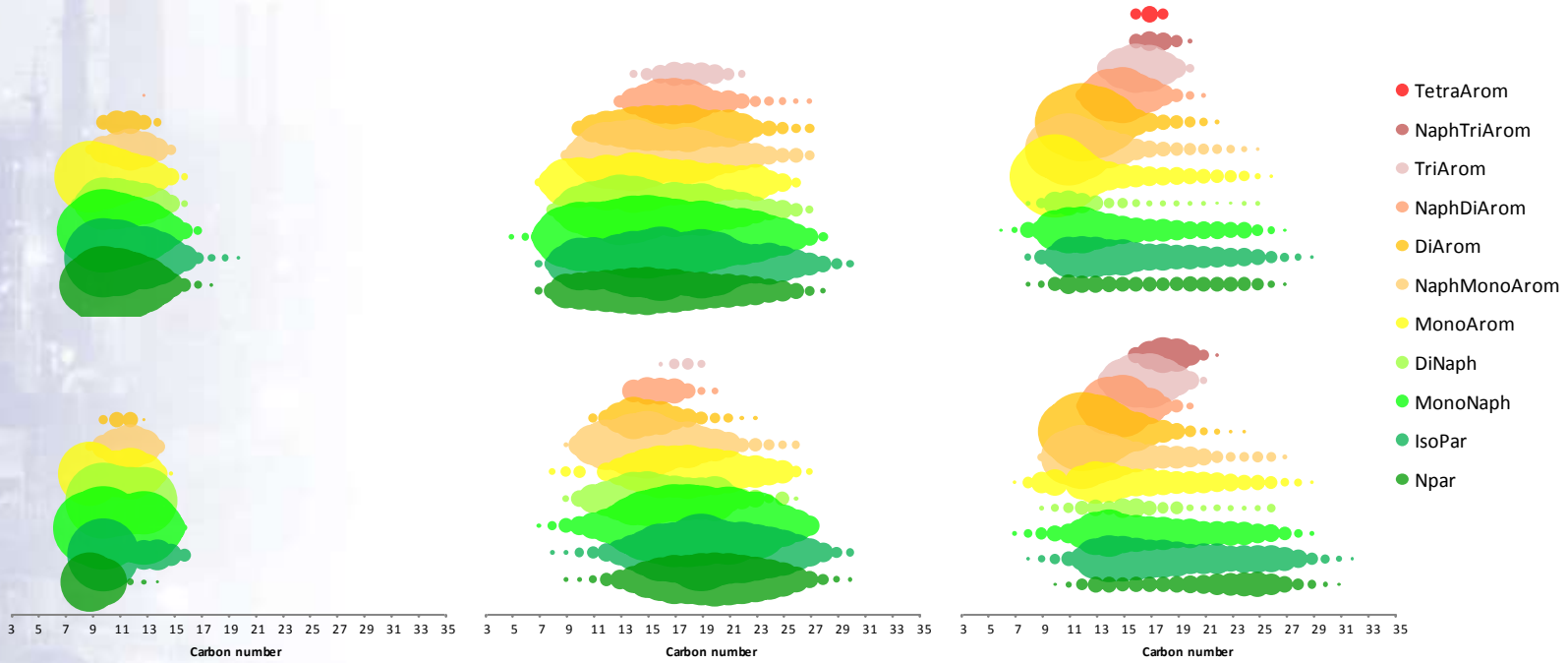
Concawe approach to REACH registration

Goal: Avoid underestimating hazards

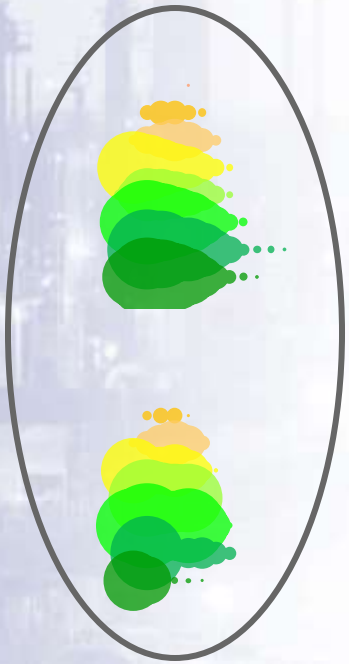
Duty on registrants: assign endpoint values & hazard classification to each substance, avoid underestimating hazards & minimize unnecessary testing.
Challenge: large number of substances with similar compositions that are variable and overlap.
6 example compositions by carbon number / hydrocarbon class



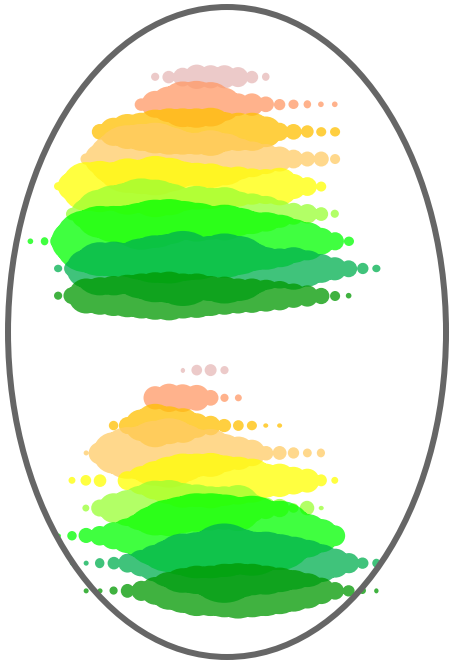
Category approach

1. Group substances of similar composition based on process history & carbon number / boiling point range
2. Per endpoint, identify value or hazard driver(s)
3. Fill in data gaps by read-across from worst case (health) or model (env)

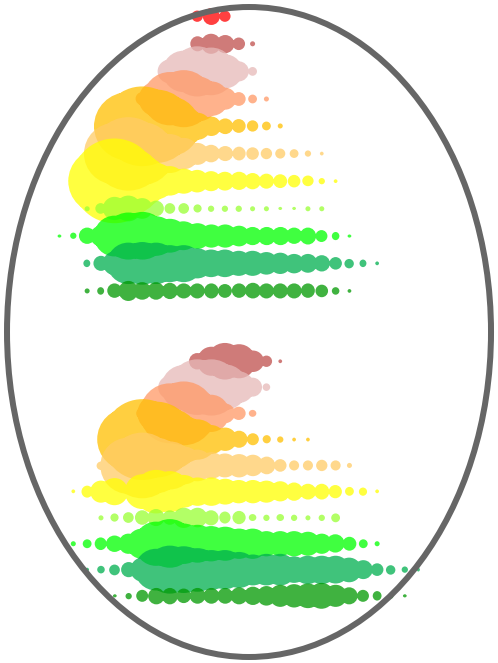
Kerosines



Vac/HC gas oils / dist fuels



Cracked gas oils (CMR)



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Challenges of REACH Evaluation 2012-2016

Evaluation issues

- Formal process: ECHA Evaluating our dossiers:

  Draft (DD) & Final Decisions (FD) received:

  - Requirement to change to Extended One Generation Reprotoxicity Studies: Comitology has now formally adopted EOGRTS. (DD)
  - Challenge to Concawe category approach & substance ID. (D&FD)
  - Challenge to our environmental tox. Models (PETROTOX, PETRORISK). (FD)

- Issues raised in dialogue
  - Substance identity / compositional data
  - Hazard assessment / category approach to read-across
  - PBT assessment
  - Classification & Labelling
  - Potential exposure / use

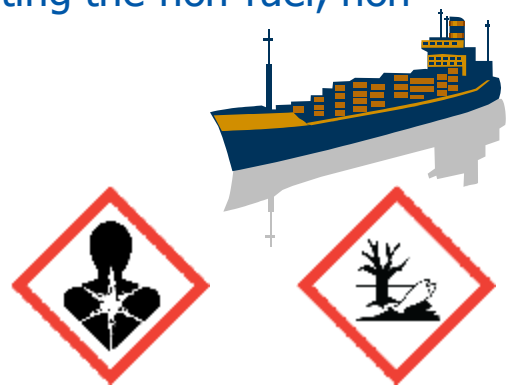
Substances of Very High Concern (SVHC)

The EU COM SVHC Roadmap (assessment from 2016):

Select substances for assessment based on:

1. High volumes in wide dispersive uses, specifically targeting the non-fuel, non-intermediate uses of Petroleum Substances (PS):

2. Properties, specifically:
   - CMR (Carcinogenic, Mutagenic or toxic for Reproduction).
   - PBT (Persistent, Bioaccumulative, Toxic) in the Environment.
   - EDR (Endocrine Disruptive);



Concawe strategy:

1. Minimise the number of PS that are added to the SVHC list.
   - In Concawe CSA's, Fuels is the only consumer use for PS that is classified as carcinogenic.

2. Demonstrate that current RMMs* are effective for 200 registered PS.
   - 25% - 50 PS are "unconditional" CMRs
   - 60% - 120 PS are "conditional" CMRs

   Only non-CMR substances are supported for non-fuel consumer uses

*Risk Management Measures

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Concawe REACH strategy and plan 2015-2019

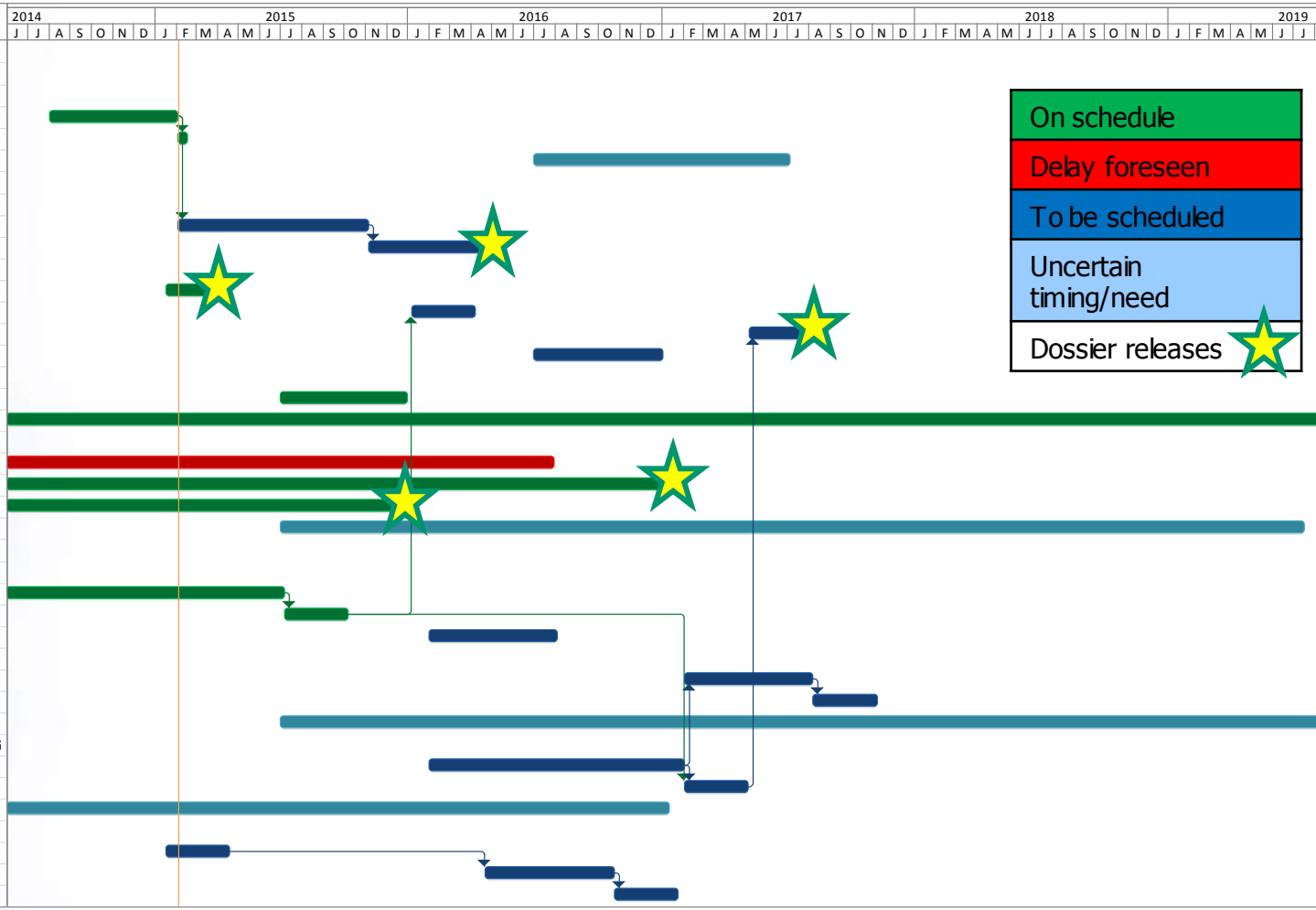
REACH Goals

Concawe's key goals for REACH are to:

1. Sustain the safe use of Petroleum Substances (PS) with no unwarranted restrictions.
2. Support Member Companies (MCs) to comply with REACH & CLP in the most efficient way, and in so doing, consider total cost for MCs, not just Concawe cost.
3. Achieve a workable approach that takes into account the complexity of PS UVCBs.

REACH 2015-19 workplan

ID	Task Name	Lead
0	**Concawe REACH delivery**	
1	**Sustain safe uses w/o u/w restrictions**	
1.1	**Tiered use map (SVHC)**	**PPMG**
1.1.1	Complete volume/use survey	
1.1.2	Summarize use analysis into tiers	
1.2	*Authorisations if needed*	
2	**Support companies to comply efficiently**	
2.1	**Updated dossiers for IUCLID 6**	**IPT**
2.1.1	Transcribe exposure scenarios to 3.7	
2.1.2	Update dossiers and software	
2.2	**Classification & Labelling**	**STF-23**
2.2.1	Comply with 4th ATP & 5th (1 naphtha dossi	
2.2.2	Refresh with revised category structure	
2.2.3	Link to updated hazard assessment	
2.2.4	Propose harmonized classifications for Note	
2.3	**SIEF management**	**SMCG**
2.3.1	2018 licensing model	
2.3.2	*Dossier distribution, cost sharing & support*	
2.4	**PNDT for bitumens**	**TSG**
2.4.1	Bitumen category 92062-05-0	
2.4.2	Oxidized asphalt 64742-93-4	
2.5	***PNEC derivation***	***EG***
2.6	*Reprotox for bitumens/gasoils/RAE*	*TSG*
3	**Agree workable treatment for complexity**	
3.1	**Revised category definitions**	**SIG**
3.1.1	Complete analytical program	
3.1.2	Derive category composition ranges	
3.1.3	Implement substance-level phys/chem	
3.2	**Revised substance identity**	**SIG**
3.2.1	Perform composition survey	
3.2.2	Derive substance composition ranges	
3.3	*Toxicogenomics research program*	*TSG*
3.4	**Upgraded hazard read-across**	**TSG,EG**
3.4.1	Document read across hypotheses	
3.4.2	Review hypothesis support in compositions	
3.5	*Environmental fate research program*	*EG*
3.6	**Updated PBT assessments (SVHC)**	**EG**
3.6.1	Publish pending reports	
3.6.2	Review completeness & reasoning	
3.6.3	Share informally and in dossiers	



We need company support!

Co-operative approach of Concawe acknowledged by authorities but Concawe leadership relies on practical support of companies to achieve shared goals.

Concawe projects

- Contribute to surveys on use, composition, properties etc.
- Provide samples when requested

Dossier updates

- Follow SIEF Newsletter
- Obtain latest dossier, don't change common parts
  - including C&L, SDS to be aligned
- Maintain company-specific parts (including appropriate substance ID)
- Submit updates on time (especially LR's)

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Thank you