

Reporting use and exposure information in IUCLID

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- ▶ The EU Commission SVHC Roadmap states that "*there is a need to develop an approach to assess the petroleum streams (approach 2013-2015, systematic assessment from 2016).*"
- ▶ The 2010 REACH registration dossiers for Petroleum Substances contain Tonnages per Use per Category* whilst regulatory processes (e.g. SVHC assessment) take place at the Substance level
- ▶ Therefore, in July 2014 Concaawe sent Questionnaires to all registrants of Petroleum Substances, requesting information on Tonnages per Use per Substance per Legal Entity for the year 2013
 - ▶ The Tonnages are aggregated per Substance before sharing outside Concaawe to protect the confidentiality of the information
 - ▶ 2013 data are considered historical and can be used without infringing Competition Law

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* A Category is a group of substances with similar properties



- ▶ The scope (i.e. number of registrations) of the Use survey is hard to define since:
 - ▶ Concaawe does not have complete information on the UUIDs of the registering Legal Entities (registrants do not always inform Concaawe of changes)
 - ▶ The information in ECHA Dissemination website only gives the Legal Entity names and provides only one entry when the same Legal Entity name has been used for more than one UUID
 - ▶ Ownership changes, Bankrupted companies, Cease of Manufacture, etc. further complicate the picture
- ▶ Combining the information from Concaawe and from ECHA Dissemination website (as of 18 June 2015), there are **4,468** registrations using (or having used) Concaawe dossiers for **207** Petroleum Substances by **735** Legal Entities
- ▶ In terms of registrations, the data received by Concaawe reach **100 %** for Concaawe members and **63.7 %** for non-members with an overall figure of **88.0 %**; all missing Legal Entities are non-members and Concaawe often does not have a working e-mail contact for them



- ▶ A significant number of registrants could not be reached
- ▶ Many interactions (thousands of e-mails!) with registrants were needed before being able to clarify the Use pattern of Petroleum Substances
- ▶ 150 million tonnes were initially reported as “sold to traders / distributors” (many Petroleum Substances are traded as commodities)
- ▶ Collaboration with registrants resulted in the full allocation of all EU Tonnages to specific Uses as provided in the Concaawe Questionnaires
- ▶ Difficulties were often found by registrants to understand exactly what was covered by a specific Use

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Analysis of Tonnages

Use setting	Million tonnes
Manufactured	821
Imported	199
Exported	51
Intermediate Use (not under Strictly Controlled Conditions)	324
Marketed = Manufactured + Imported – Exported – Intermediate Use	645
Fuel	609
Industrial (non-Fuel)	16
Professional (non-Fuel)	20
Consumer + Articles (non-Fuel)	2
Widespread (non-Fuel) = Professional + Consumer + Articles	22

- ▶ Although only $22/(821+199-51) = 2.3 \%$ of the EU Tonnage goes into Widespread uses, the absolute figure (**22 million tonnes**) is significant

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A legal review will be completed, to ensure the proposed steps below are done in compliance with Competition Law

- ▶ Quality checks will be conducted to confirm uses reported in less than 3 registrations
- ▶ After consultation with SIEFs, uses with no reported tonnages will be removed from the dossiers
- ▶ After consultation with SIEFs, several uses may be included in the dossiers as “Uses advised against”

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- ▶ Concaawe will consider reporting the “joint” Tonnages per Use per Substance as “total EU tonnage” in IUCLID6 Section 3.5
- ▶ This information will be generated by Concaawe and submitted only in the Lead registrants dossiers
- ▶ **This will happen only if this business-sensitive information will not be disseminated**

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- ▶ 1000* Exposure Scenarios (Uses x classified Substances) x 200 fields (estimated IUCLID5.6.0.2) + 8000 Contributing Exposure Scenarios x 100 fields (estimated IUCLID5.6.0.2) = **1 million** input fields; **this cannot be done manually!**
- ▶ The figure above can change (upwards or downwards) since:
 - ▶ The final structure of 3.7 in IUCLID6 may contain more fields
 - ▶ A number of fields may be irrelevant and therefore could be left empty
- ▶ Concaawe is currently exploring the use of CHESAR to generate the Health Risk Assessments and to investigate the automatic population of 3.7
- ▶ The Environmental Risk Assessments are carried out with PETRORISK and its Excel output is expected to be suitable for automatic population of 3.7
- ▶ **The decision to populate Section 3.7 will be taken after a thorough cost-benefit analysis (plus assessment of time and resources)**

* Assuming that the assessments will have to be done per Substance rather than for the whole Category as in the 2010 dossiers



CONCLUSIONS

- ▶ This exercise has taken 1 man-year of effort at Concaawe, plus significant resources from registrants
- ▶ The collection of Uses data for Petroleum Substances has been beneficial for the following reasons
 - ▶ The Use pattern has been clarified vs. the all-inclusive approach taken in 2010, resulting in a significantly smaller number of Uses (for classified Substances) to be assessed (from 323 down to 220)
 - ▶ The allocation of Tonnages (and related hazard classifications) to Uses is key to guide the prioritization for the SVHC Roadmap, resulting in a significant reduction of the number of Substances in scope (from 207 down to 65)

Concaawe wishes to thank registrants for their collaboration

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