



# Industry reflections on substance identity SID WS ECHA 6 – 7 October 2014, Helsinki



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# Recital 33 of REACH

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- **Joint submission** and the sharing of information on substances should be provided for in order to **increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals.** One of a group of multiple registrants should submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden. A registrant should be able to submit information directly to the Agency in certain specified cases.

# Recital 45 of REACH

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- The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. **UVCB substances** (substances of unknown or variable composition, complex reaction products or biological materials) **may be registered as a single substance** under this Regulation, despite their variable composition, **provided that the hazardous properties do not differ significantly and warrant the same classification.**

# Joint submission

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- **Joint submission intrinsically means**
  - **A recognition of possibility of substance sameness**
- **Joint submission requires**
  - **The identification requirements per registrant**

# Substance sameness

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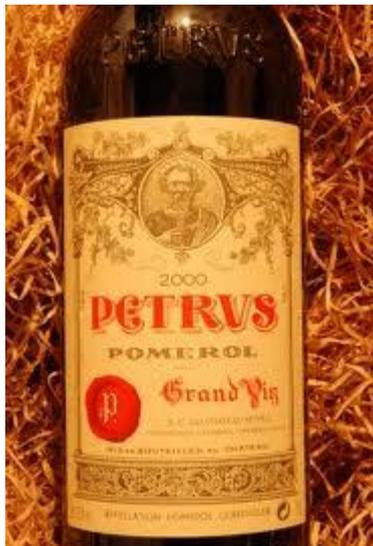


- **A philosophical concept**
  - **Every substance is different**
  - **But how different is different to become a different substance?**
    - **Different grades as pro analyse, pure, technical are the same substance**
      - **Some rules are given in the guidance for monoconstituent substances and multi-constituent substances, although more related to substance identity**
    - **Off spec material compared to some product specifications will be nearly always the same substance**

# What's different for some people...



- May be the same, when talking about substance sameness under REACH



# What did Cefic do?

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- **Prepare its members and all companies for REACH**
  - **In 2008 we decided to publish all our REACH documents openly on our website**
  - **Our documents were downloaded enormously**
  - **They contained reflections on all aspects, including substance identity**
  - **But written from a generic approach covering as much as possible the classical chemical industry experiences and understanding at a specific moment in time**

# What did ReachCentrum do?

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- They worked with the documents in a real world environment of managing SIEFs
- The daily work of SIEF management required a more practical approach
- The Substance Identification Profile (SIP) is the result
- In many cases it has been handled by a trustee
- ReachCentrum agreed to share this with the world via the Cefic website
- The SIP as available on our website is for monoconstituent substances
- A consultant has a version for multiconstituent substances and for UVCB, that will be made available soon on his website

# Comments on the background document

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- **Basic Principle on UVCB SID should be “one dataset – one registration”.**
- **The same registration conditions must apply for all registrants under REACH, independent from transitional period applicable. Therefore ECHA should not change any rules regarding SID. It may create quite some additional burden.**
- **In principle it is supported that ECHA’s starting point is the approach under EINECS as substance identification practice has been based on EINECS definitions and experiences.**
- **We appreciate that ECHA wants to focus discussions on the question “what” can be registered together.**

# Comments on the background document

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- We also appreciate that ECHA recognizes that in practice expert judgment and decisions have to be taken for non-simple cases by including a category “Joint registration is plausible, if justifiable”
- As in EINECS a combination of the 3 depict is accepted, it should also be maintained in ECHAs concept for UVCB

# Comments on the background document

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- **Recital 45 of REACH clarifies that UVCB substances can be registered together “despite their variable composition”. There is no limitation foreseen via this recital and nowhere else with regard to possible percentages of components. But there is a limitation by classification mentioned in the recital. This limitation is not in line with the approach taken for other substances where different classifications are no “no go” for a joint registration.**
  - **This should not be in contradiction with the CLP Regulation, where in Annex VI part 3 the notes J, K, L, M, N and P can result in a different classification for the same UVCB**

## Comments on the background document

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- Whereas already for the UVCB with sameness according to structural representation we see no legal mandate for restrictions by the 80/20 or 80/10 rule, such approach is per se not transferable to a common reaction scheme and process output.

# Conclusions

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- **General principles for discussion on substance sameness should not be too rigid and allow a case-by-case approach where needed**
- **But although all cases are unique, it remains interesting to focus on a general approach that is overarching but leaving the necessary flexibility.**

# Conclusions

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- **Seven years after the publication of the guidance for identification and naming of substances under REACH, there is much more practical experience available**
- **A discussion on sameness (not even mentioned in the title of the guidance) is important to have a better understanding from industry and authorities**
- **Clarifications are welcomed in view of the upcoming 2018 registration deadline, but should not change the REACH requirements**



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**Thanks for your attention**