



# PGMs Sameness Experts Group Meeting

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29 JUNE 2015, BRUSSELS



## 1. Welcome and introduction

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# 1.1. Competition law and confidentiality



DO	DON'T
<p><b>Application of competition law</b> Art. 101 and 102 TFEU may be applicable to the conclusion of any preliminary agreement and activities of any preliminary phase.</p>	<p>Don't assume that conflicts with competition law are excluded simply by the fact that the Agreement complies with the provisions of the REACH Regulation.</p>
<p><b>Consultation in Matters of Competition Law</b> Consult an in-house legal expert or the compliance officer of your company or an external lawyer whenever there are uncertainties respecting compliance with competition law. Stop all meetings/discussions which are not in compliance with these Compliance Guidelines until a legal expert has been involved.</p>	<p>Don't assume that these Compliance Guidelines deal with all competition law issues exhaustively. Basically, compliance with Art. 101 and 102 TFEU can be determined only on the basis of market impact in each individual case. These Compliance Guidelines may therefore be regarded only as a means of providing general conduct recommendations.</p>
<p><b>Activities in any preliminary phase and at any other stage of operation of the Consortium</b> Restrict cooperation within the scope of the preliminary phase to the initially defined goals and purposes of the cooperation.</p>	<p>Pursuant to Art. 101 and 102 TFEU, activities which have the object or the effect of preventing, restricting and/or distorting competition are prohibited within the scope of this Agreement, including:</p> <ul style="list-style-type: none"> <li>- Coming to agreement, including arrangements or collusions, about prices, markets and customers (see Art. 101 paragraph 1(a)-(c) TFEU);</li> <li>- Joint boycotting of other companies;</li> <li>- The unjustified unequal treatment of trade partners;</li> <li>- The abusive exploitation of a dominating market position.</li> </ul>
<p><b>Exchange of Confidential Information</b> Involve a Trustee for the exchange of Confidential information.</p>	<p>The exchange of information concerning market behaviour and having the object or the effect of preventing, restricting and/or distorting competition is inadmissible; in particular, this relates to:</p> <ul style="list-style-type: none"> <li>- Production capacities;</li> <li>- Production or sales volumes;</li> <li>- Import volumes;</li> <li>- Market shares;</li> <li>- Price policy;</li> <li>- Distribution and marketing terms;</li> <li>- Marketing strategies;</li> <li>- Information regarding the relationship with suppliers.</li> </ul>
<p><b>Documentation on Cooperation</b> Keep minutes of all meetings which detail the subject of the meeting. In case of uncertainty, have the contents of the minutes reviewed by an external legal expert prior to sending them to all parties of the Agreement. Stop all meetings which are not in compliance with these Guidelines until a legal expert has been involved.</p>	

# 1.2. Tour de table





## 1.3. Approval of the agenda

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- “Welcome and introduction
- “Background/ Reach requirements
- “Hydrated vs. anhydrous forms
- “Substances available only in solution
- “Conclusions
- “AOB, next meeting and closing remarks

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## 2. Background/ Reach requirements

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## Reach requirements

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### Guidance

- 'ECHA Guidance for identification and naming of substances under REACH and CLP'
- Guidance currently under review, but no new guidance available = need to work on basis of existing guidance

### Sameness

- 80% rule applies
- Also for UVCBs, but more information required (reaction scheme, process, etc.)

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## Reach requirements

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### Substance Identification (SID) of mono-constituent samples

- Main constituent (>80%) + all known Impurities >1%. Composition should add up to 100%
- Additives (under Reach)
  - Intentionally added to stabilize the substance = no impurities
  - Contributes to the composition but not the substance name
  - Should always be fully identified

### Substance ID of UVCBs

- No 'impurities'
- ID all known constituents as far as possible
- Constituents >10% need IUPAC name + concentration range
- Constituents relevant for classification: no threshold

PMC will circulate and finalise SID cards for all PGMs in Q3 2015

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## Reach requirements

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### Analytical requirements

- Need to be able to sufficiently describe the substance
- Provide information mentioned in Guidance:
  - If it contributes to substance ID
  - If not relevant, put waiver. Need to provide good justification
  - Cf. PMC guidance for minimum analytical requirements

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## 3. Hydrates vs. anhydrous forms

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## Definitions

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### Draft Guidance for Annex V

*Hydrates of a substance are characterised by the fact that water molecules are linked, in particular by hydrogen bonds, to other molecules or ions of the substance. A substance that does not contain any water is referred to as anhydrous. Solid hydrates contain water of crystallization in a stoichiometric ratio*

**Wikipedia** (<https://en.wikipedia.org/wiki/Hydrate>)

*Hydrates are inorganic salts "containing water molecules combined in a definite ratio as an integral part of the crystal that are either bound to a metal center or that have crystallized with the metal complex. . . . A hydrate which has lost water is referred to as an anhydride*

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## How are hydrates handled under Reach?

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### ECHA "Guidance for identification and naming of substances under REACH and CLP"

*"Hydrated and anhydrous forms of compounds shall be regarded as the same substance for the purpose of a registration. . . . Hydrated and anhydrous forms have different chemical names and different CAS numbers. Detailed information on how to make use of the specific provision for the registration of hydrated forms of a substance in Annex V(6) of the REACH Regulation, is given in the Data Submission Manual Part 18 – "How to report the substance identity in IUCLID 5 for registration under REACH"*

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## How are hydrates handled under Reach?

### ECHA 'Data submission Manual'

- *'the anhydrous form of a substance and any of its hydrated forms are regarded as different substances. If you want to make use of the specific provision for the registration of hydrated forms of a substance in Annex V(6) of the REACH Regulation, you should prepare a registration for the anhydrous form of the substance and report all the different compositions covered by the registration in section 1.2.'*

### 'Draft Guidance for Annex V'

- *'For the purposes of this Annex, hydrates and water free forms (anhydrous) of compounds shall be regarded as the same substance despite the fact that hydrated and anhydrous forms of the substance can have different chemical names and different CAS numbers.'*
- *A registrant who wants to make use of the exemption under this entry needs to add up the quantities of the anhydrous form and the different hydrated forms in his technical dossier (but excluding the water which is attached to the parent molecule).*

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## Hydrated and anhydrous forms can have different properties



Hydrated copper(II)  
sulfate is bright blue.



Anhydrous copper(II)  
sulfate is white.

Source: Wikipedia

← Same substance under Reach

### Wikipedia

*In some cases, the degree of hydration can be critical to the resulting chemical properties. For example, anhydrous  $RhCl_3$  is not soluble in water and is relatively useless in organometallic chemistry whereas  $RhCl_3 \cdot 3H_2O$  is versatile. ([https://en.wikipedia.org/wiki/Water\\_of\\_crystallization](https://en.wikipedia.org/wiki/Water_of_crystallization))*

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## Proposed Strategy

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“PMC default approach: ‘hydrated’ forms will be registered in the same dossier as the anhydrous forms

“Caveat: Need to correctly determine the substance volumes (cf. previous slide)

“Any objections?”

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## Discussion

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## 4. Solutions

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## Definitions

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### REACH regulation (Article 3(1))

*A "Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"*

### ECHA "Guidance for identification and naming of substances under REACH and CLP"

"Additive: A substance that has been intentionally added to stabilise the substance." ( . . . )

"Additives contribute to the substance composition (but not to the naming) and should always be fully identified."



## Proposed Strategy

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- Default strategy: register the substance as such and consider solutions as mixtures
- Exception: substance is not stable without solvent (= 'Additive')
  - Register solution
  - Caveat: need to consider solvent when determining tonnage band!
- Any objections?

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## Discussion

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## 5. Conclusions

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## 6. AOB, next meeting and closing remarks

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