

# WORKSHOP on SUBSTANCE IDENTIFICATION and 'SAMENESS'

6 – 7 OCTOBER 2014

ECHA CONFERENCE CENTRE, ANNANKATU 18, HELSINKI, FINLAND

## AGENDA

<b>MONDAY 6 OCTOBER 2014</b> <b>CHAIR: CHRISTEL MUSSET</b> <b>(DIRECTOR OF REGISTRATION)</b>	
<b>13:30-14:00</b>	<b>Registration of participants</b>
<b>14:00-14:10</b>	<b>Welcome and Introduction</b> (by Geert DANCET – Executive Director, ECHA) <ul style="list-style-type: none"><li>- <i>Importance of substance identification (SID) and substance sameness in REACH and CLP processes.</i></li></ul>
<b>14:10-14:30</b>	<b>Setting the scene (1)</b> <b>Background to the workshop</b> (by Guilhem DE SEZE – Head of Unit Substance Identification and Data Sharing, ECHA) <ul style="list-style-type: none"><li>- <i>A few past milestones of Substance Identification under REACH</i></li><li>- <i>SID challenges ahead</i></li><li>- <i>Objectives of the workshop</i></li></ul>
<b>14:30-14:50</b>	<b>Setting the scene (2)</b> <b>Rights and obligations resulting from SID considerations</b> (by Cyril JACQUET – Legal Affairs Unit, ECHA) <ul style="list-style-type: none"><li>- <i>Legal and scientific dimensions of SID</i></li><li>- <i>Legal aspects to be solved</i></li></ul>
<b>14:50-15:00</b>	<b>Q&amp;A</b>
<b>15:00-15:30</b>	<b>MSCAs' experience on SID and substance sameness (1)</b> <b>From substance identification to experiences from SID checks</b> (by Kristof SEUBERT – BAuA, German Competent Authority) <ul style="list-style-type: none"><li>- <i>the identification of complex substances</i></li><li>- <i>deciding on sameness in a joint submission</i></li><li>- <i>SID deficiencies that make sameness discussions difficult</i></li><li>- <i>Examples of inconsistencies</i></li></ul>

<b>15:30-15:40</b>	<b>Q&amp;A</b>
<b>15:40-16:10</b>	<b>Coffee break</b>
<b>16:10-16:40</b>	<p><b>MSCAs' experience on SID and substance sameness (2)</b></p> <p><b>Substance identification in Substance Evaluation – the French CA experience</b></p> <p>(by Cecile MICHEL – ANSES, French Competent Authority)</p> <ul style="list-style-type: none"> <li>- <i>Examples of SID issues from various substance evaluation cases</i></li> <li>- <i>Scope of the JS registration</i></li> <li>- <i>Establishing the relevance of the test substance used to generate the data for the various compositions in a Joint Submission</i></li> </ul>
<b>16:40-16:50</b>	<b>Q&amp;A</b>
<b>16:50-17:30</b>	<p><b>Substance sameness – concepts and development of a methodology</b></p> <p>(by Ronan NICOLAS – ECHA, Substance Identification and Data Sharing Unit)</p> <p><i>Describing the founding principles of substance sameness and a proposed approach forward to further clarify existing guidelines; illustrative examples</i></p>
<b>17:30-17:50</b>	<b>Panel discussion</b>
<b>17:50-18:00</b>	<b>Wrap-up (1<sup>st</sup> day)</b>
<b>18:00-19:00</b>	<b>End of Day 1 - Cocktail reception</b>

<b>TUESDAY 7 OCTOBER 2014</b> <b>CHAIR: GUILHEM DE SEZE</b> <b>(HEAD OF UNIT SUBSTANCE IDENTIFICATION AND DATA SHARING)</b>	
<b>09:00-09:05</b>	<b>Recap from Day 1 and short introduction to Day 2</b> <b>Challenges faced by registrants to establish substance sameness</b>
<b>09:05-09:40</b>	<b>CEFIC: General approach on substance 'sameness'</b>  <b>a) Industry reflections on substance identity</b> (by Erwin ANNYS - CEFIC) <ul style="list-style-type: none"> <li>- <i>Joint submission and sharing information on substances</i></li> <li>- <i>A philosophical concept - every substance is different, but how different must it be to become a different substance?</i></li> <li>- <i>CEFIC experience since 2008</i></li> </ul> <b>b) Hydrocarbon solvents</b> (by Paula Karjalainen - Neste Oil Oy) <ul style="list-style-type: none"> <li>- <i>Substance identification, compositional information, and manufacturing process,</i></li> <li>- <i>Technical requirements for Hydrocarbon solvents</i></li> <li>- <i>Issues related to substance identification</i></li> <li>- <i>Naming convention</i></li> </ul>
<b>09:40-09:50</b>	<b>Q&amp;A</b>
<b>09:50-10:20</b>	<b>CONCAWE: Specific features of Petroleum UVCB Substances</b> (by Stephen Harley, BP) <ul style="list-style-type: none"> <li>- <i>Identity and complexity of petroleum substances – how these relate to REACH (and SID parameters).</i></li> <li>- <i>Importance of criteria like feedstock (source) and description of the process, boiling range as well as EINECS description; e.g. carbon range</i></li> </ul>
<b>10:20-10:30</b>	<b>Q&amp;A</b>
<b>10:30-11:00</b>	<b>Coffee break</b>
<b>11:00-11:30</b>	<b>Eurometaux: inorganic UVCBs</b>  <b>Experience from non-ferrous metal industry in establishing substance sameness</b> (by Katia LACASSE , Copper Alliance & Katrien ARIJS, Arche Consulting)

	<ul style="list-style-type: none"> <li>- <i>Inorganic UVCBs</i></li> <li>- <i>Refining processes</i></li> <li>- <i>SIEF formation</i></li> <li>- <i>Challenges and solutions</i></li> <li>- <i>How is/was variability addressed?</i></li> </ul>
<b>11:30-11:40</b>	<b>Q&amp;A</b>
<b>11:40-12:30</b>	<b>Panel discussion</b>
<b>12:30-13:30</b>	Lunch break

<b>TUESDAY 7 OCTOBER 2014</b>	
<b>BREAKOUT GROUPS – REPORTS - CONCLUSIONS</b>	
<b>13:30-15:00</b>	<p><b>4 Breakout groups for different industry sectors/different substances, running in parallel:</b></p> <ul style="list-style-type: none"> <li>1 - <i>Petroleum substance</i></li> <li>2 - <i>Hydrocarbon solvents</i></li> <li>3 - <i>Metals</i></li> <li>4 - <i>Organic dyes</i></li> </ul> <p><b>Discussing how to assess sameness of complex substances</b></p> <p>a) <i>How to apply the 3 steps sameness methodology and criteria to real cases? How to handle deviations?</i></p> <ul style="list-style-type: none"> <li>1. <i>Structural representation</i></li> <li>2. <i>Reaction scheme</i></li> <li>3. <i>Process output</i></li> </ul> <p>b) <i>How to ensure transparency of the substance sameness approach, when it cannot be presumed that the properties of substances will be sufficiently constant within the permissible variations in the composition?</i></p>
<b>15:00-15:30</b>	<b>Coffee break</b>
<b>15:30-16:10</b>	<p><b>Report from Breakout groups</b></p> <p><i>Each rapporteur to present the outcome of the discussion</i></p>
<b>16:10-16:45</b>	<b>Panel discussion</b>
<b>16:45-17:00</b>	<b>Wrap-up and conclusion</b>
<b>17:00</b>	<b>End of Day 2</b>