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**Subject:** feedback meetings with ECHA last week on UVCBs assessment  
**Date:** 27 Jan 2014 16:10:29 GMT+01:00  
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▶ 2 Attachments, 4,7 MB

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### To the Intermediates Taskforce

We hope you are all doing fine.

Please find herewith some feedback on two meetings we had with ECHA last week, related to our inorganics UVCB assessment and reporting.

The **first meeting (22<sup>nd</sup> of January)** was set up by ECHA's scientific adviser, as a follow-up meeting of the discussions we had in May 2012, January 2013 and October 2013. Its main objective was to explain the proposed CSA flow, illustrated by a pilot case (Cu slimes). The meeting was (well) attended by ECHA experts from the SID, Classification, Evaluation and Computational units. Both industry and the SID unit made presentations. The presentations are attached.

Before moving on to the feedback from ECHA, we would like to sincerely thank Katia, Daniel, Frederik and Hugo who invested a lot of energy and time in preparing and handling these meetings. Although the atmosphere was very constructive, the meeting of the 22<sup>nd</sup> was not an "easy-ride" as the questions we got back from ECHA, reflecting their own views and interests, were quite technical and challenging. But the metals team appeared credible, consistent and scientifically well prepared, which is a great achievement J. Thanks again

Thanks as well to Caroline, Katrien, the ARCHE staff who helped with the preparation and the continuity over the Christmas break and early January!

The meeting on the 22<sup>nd</sup> concluded that in general, the presented approach appeared acceptable to ECHA. Several areas for improvement were however identified. These mainly concern **readability** of the approach (wording, structure and use of a common terminology), the **format** for reporting (that should allow an independent and transparent assessment), the need to well **justify** any deviation from the REACH guidance, clarifications on the **data access** we have and how we are using the data in the assessment. On a long term, it was also recommended to work on the publication/documentation of our tools and databases (e.g. MeClas, MEASE, Multi-metallic database).

From a scientific point of view, pending challenges are the combined toxicity and the need to reflect on the validation of the proposed approach.

In the overall CSA flow, the **Substance Identification** aspects and their consideration throughout the assessment also need further work on the mutual ECHA/industry understanding. As you will see from the ECHA SID slides (in particular slide 15), some of the current hurdles are related to the way we grouped and identified substances before 2010, the evolving SID guidance and misinterpretations. We proposed to the SID unit to visualize the process flow and ask their questions *in vivo*, at a plant. Thanks to Katia and Mika,

this plant visit should take place on February 14.

A key message, stated repeatedly by ECHA, is that we need to submit our 'upgraded dossiers' end of April. They want to be able to discriminate between registrants following up on previous ECHA actions/agreements and others (further enforcement actions planned).

They realise however the tight timelines we are confronted with and that the dossiers that will be submitted end of April will not have solved all pending/improvement issues that were identified last week. Several of those issues may require updates. Also the formatting/reporting aspect is not something we, as industry, should work on in isolation: the evaluation and computational units will work in parallel.

In view of all this, ECHA proposed us to come back to them with a **roadmap of actions**: which actions will we carry out, how, what is their priority (high, medium, low) and their timing perspective (long, medium, short-term)? This would also give them an idea of timing and e.g. allow them not to start compliance checks on the dossier we will submit in April as they know an update will follow with this or that aspect.

Clearly a number of detailed technical actions have now to be reflected on and implemented by the consultants in charge of the drafting of the dossiers. In view of this, we would like to ask you –in case you are working with other consultants than EBRC and ARCHE, to inform them of the outcomes of the meeting and ask them to contact us. Also it seems that only 37/60 Article 10 dossiers expected in April are under the EM umbrella. If you are aware of any other, please inform us. **Consistency will be key to avoid evaluation activities.**

The **second meeting (23<sup>rd</sup> of January)** focused on “reporting aspects”, not only associated with our UVCBs but also with metals' assessment. It was attended by experts from ECHA's computational unit only. The main objectives here were to discuss aspects in IUCLID and Chesar that are currently not fitting well with the metals approaches and find together some ways forward. How to report our UVCBs assessment in IUCLID was also discussed. We had very interesting discussions as well and identified some next steps. Part of those, not UVCB specific, (Chesar/IUCLID) will be further followed up by the Exposure Scenarios Taskforce. Any progress on UVCB formatting aspects will be reported to you.

We hope this email provides you with a good summary of the outcomes. If you have questions, please do not hesitate to contact us.

Wishing you an excellent start of the week,

Fè and Vio



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