MEDIUM-CHAIN CHLORINATED PARAFFINS REACH CONSORTIUM

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Date: 26 September 2013

To: Ms. Leena Ylä-Mononen, Director of Evaluation, ECHA Evaluation Directorate
Secretariat of the Member State Committee
Mr. Klaus Berend, Director REACH, DG Enterprise
Mr. Björn Hansen, Director Chemicals, DG Environment

The Medium-Chain Chlorinated Paraffins (MCCP) REACH Consortium (the "Consortium"), with support of the Euro Chlor Chlorinated Paraffin Sector Group (CPSG), is writing this letter to express deep concerns regarding the new substance evaluation of MCCP under CoRAP and the limitations in the science being employed to assess the PBT characteristics of MCCP. The CPSG, the Consortium, and previous CP trade groups have been conducting research since the 1970's to refine our understanding of the environmental risks of MCCP. This accumulated knowledge is reflected in the extensive Chemical Safety Report of MCCP. Our organisations are keen to pursue the advancement of knowledge of the environmental risks of MCCPs, but would prefer to spend resources on studies that will actually advance that knowledge.

We think that the proposed environmental fate testing:

- will not deliver what is aimed for;
- is not feasible for a substance like MCCP due to its strong sorption characteristics;
- will not deliver additional knowledge to what is already known and therefore represents a backwards development;
- does not address the key elements needed to assess the actual environmental risks of MCCP;
- focuses on narrowly selected components of this extremely complicated UVCB substance representing only a small fraction of the product and therefore producing results for just an extremely small portion of the actual substance; and,
- will face analytical hurdles which are impossible to overcome based on even the most sophisticated analytical techniques in the world.

Instead of carrying out tests on selected 'individual' components (which are UVCBs themselves), we propose to carry out tests on actual representative commercial products and their degradation products using OECD recommended test approaches based on whole effluent and water accommodated fractions testing techniques.

We also think it is a significant omission in the current procedure that industry has no possibility to discuss a meaningful testing approach with Member States (MS) as this is essential for such a complicated and challenging UVCB like MCCP.

We therefore call upon the MS PBT experts to reject the proposed testing and consider alternative means to most effectively evaluate the PBT status of MCCP. We believe the

complexity of understanding the environmental impact of this UVCB is not adequately addressed when simply following test requirements of standard PBT Guidance, it needs advanced and state-of-the-art science. The information available in the CSR and additional information provided to the RMS allows a much more sophisticated assessment than what will be achieved with the proposed testing. We have been working and continue to work on a way forward that is meaningful and cost-effective. A key concern is the request to perform OECD 308 tests which we think will not provide a relevant environmental half-life in water/sediment for MCCP. The complex set-up of this non-validated OECD test has so many variables that no clear conclusion can be drawn from its results. Based on tests already carried out we can more or less predict what the outcome will be, but moreover, this outcome will not have relevance to what can be expected under real life conditions. In addition, the limitations of even the most sophisticated analytics, even when radiolabeled material will be used, will not allow meaningful final conclusions about the environmental risks of MCCP.

On the Bioaccumulation potential assessment it is disappointing that ECHA is requesting BCF tests of low relevance for hydrophobic substances like MCCP while at the same time more meaningful test data (Trophic Magnification Factors (TMFs) and both laboratory- and field-derived Biomagnification Factors (BMFs)) are already available and indicate no bioaccumulation potential based on the overall weight of evidence. In addition the proposed testing is unlikely to deliver new information as was demonstrated by an extensive critical analysis of the current data as demonstrated in attached expert report carried out to analyse the feasibility and usefulness of the required testing by the RMS.

The CPSG and Consortium stand ready to work with ECHA and the MSs to achieve a thoughtful and scientific approach to the evaluation of MCCP. Thank you for considering the above information. Additional information regarding our concerns can be found in the May 2013 Consortium comments to ECHA and MSCA (see attached).

Please contact Dolf van Wijk, CPSG Manager, at dvw@cefic.be (+32-2-676-7370) or myself at ajaques@regnet.com (+1-202-419-1504) for additional information.

Best Regards,

Andrew M. Jaques,
MCCP REACH Consortium Manager

Attachment: Consortium comments on Draft Substance Evaluation and Decision Letter