

Members of the ECHA Board of Appeal
European Chemicals Agency
Annankatu 18
PO Box 400
FI-00121
Helsinki
Finland

Dübendorf, 7. May 2014

Regarding: Limitations of OECD TG 308 for the evaluation of persistence

Dear Madams/Sirs of the ECHA Board of Appeal

1. [REDACTED]
2. [REDACTED] on a Long-range Research Initiative (LRI) project (LRI-ECO18) that is seeking to improve strategies for assessing chemical persistence at the water-sediment interface. As a part of this project, our team has identified significant limitations and inadequacies regarding the OECD Test Guideline for Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308) and its use in the evaluation of water-sediment persistence of chemicals. Core findings of this LRI project regarding the OECD TG 308 have been identified and were given in a presentation at a 29-30 January 2014 ECETOC meeting. The full presentation is attached to this letter as Annex 2.
3. I understand that the European Chemicals Agency (ECHA) has requested industry to provide aerobic and anaerobic transformation data in aquatic sediment systems using test method EU C.24/OECD TG 308. The objective of this letter is to summarise the current status of findings and conclusion from the LRI research project regarding the OECD TG 308; and to briefly outline some of the reasons as to why OECD TG 308 might not provide much additional information beyond what can be learned from ready biodegradability tests and sorption studies with respect to the biodegradation and persistence of chemical compounds such as MCCP.

I. General limitations/inadequacies regarding OECD TG 308

4. OECD TG 308 was developed to endeavour to assess chemical persistence in a water-sediment system. Some of the general limitations and inadequacies of OECD TG 308 include the following:

- In the absence of good information of the distribution of the substance throughout the sediment, and in the absence of measurements on oxygen levels and/or microbial composition/activity at different depths of the sediment, it is not possible to distinguish between aerobic and anaerobic degradation in the sediment of OECD TG 308 studies.
- OECD TG 308 involves testing of a static system and therefore does not take into account environmental factors that may impact persistence and degradation in the environment in practice such as turbulence, which might increase phase exchange velocities and nutrient availability.
- OECD TG 308 involves high sediment : water ratios, transferring mass distribution excessively towards the sediment with the result that: (i) sorption is often the dominant process observed masking degradation; and (ii) extensive non-extractable residue formation of uncertain relevance is observed.
- The concentration measurements over time observed in OECD TG 308 studies are the result of an interplay of sorption and degradation processes. Even with sophisticated parameter estimation methods, it is not possible to derive robust kinetic information on degradation in sediments. Given the high costs of OECD TG 308 studies, these inadequacies of OECD TG 308 to provide scientifically robust degradation data are of concern.

II. Little additional information to be gained from OECD TG 308 for MCCP

5. The general limitations regarding OECD TG 308 may be amplified depending on the test material.

- Bioavailability of highly hydrophobic compounds such as MCCP and many of its degradation products will be very low in OECD TG 308 studies, with only a very small fraction dissolving into the water phase. Mineralization can therefore be expected to be minor over the test period. This will most likely result in a total system half-life that is high (>100 d) and highly uncertain.
- The MCCP commercial product is a complex mixture of components, potentially composed of tens of thousands of isomers. There are limitations on the detection and quantification of individual MCCP components and degradation products even when using state-of-the-art analytical techniques. Therefore, without an unjustifiable effort on the analytical side, it would not be possible to distinguish between the parent compound pool and the metabolite pool(s) as technically required in OECD TG 308. This would make it impossible to derive any other kinetic endpoint from the study results beyond

the total system mineralization half-life. Thus, no relevant endpoints for exposure assessment could be derived from the data.

- Overall, the limitations and inadequacies of OECD 308 TG and the particular challenges with MCCP commercial products will severely limit the possibility to obtain any new information from the test with respect to the biodegradation and persistence of chemical compounds such as MCCP beyond what is already known from ready biodegradability tests and sorption studies.

[REDACTED]

[REDACTED]

[REDACTED] Fenner
Environmental Chemistry

Signed on 7. May 2014, Dübendorf

Enc: Annexes

- Annex 1: Curriculum Vitae
- Annex 2: Presentation dated 30 January 2014 entitled "Identifying limitations of the OECD water-sediment test (OECD 308) and developing suitable alternatives to assess persistence"