

Announcement of appeal¹

Case A-004-2014

Appellants ALTAIR CHIMICA S.P.A., Italy

CAFFARO INDUSTRIE S.P.A., Italy

FORTISCHEM a.s., Slovakia

INEOS Chlorvinyls Limited, United Kingdom INEOS ENTERPRISES France ZI, France

Kaustik Europe B.V., Netherlands Leuna-Tenside GmbH, Germany

Prakash Chemicals Europe B.V., Netherlands

QUÍMICA DEL CINCA, S.L., Spain

Appeal received on 16 May 2014

Subject matter A decision taken by the European Chemicals Agency (the 'Agency')

pursuant to Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation') and in accordance with the procedure set out in

Articles 50 and 52 of the REACH Regulation

Keywords Substance evaluation – Request for further information

Contested Decision ECHA Decision of 25 February 2014 on the evaluation of alkanes,

C14-17 chloro (Medium-chain chlorinated paraffins, hereinafter the

'MCCP').

The Decision was notified to the Appellants with the following annotation numbers: SEV-D-2114273983-36-01/F, SEV-D-2114273973-37-01/F, SEV-D-2114273975-33-01/F, SEV-D-2114273969-26-01/F, SEV-D-2114273977-29-01/F, SEV-D-2114273979-25-01/F, SEV-D-2114273978-27-01/F

Language of the case English

Remedy sought by the Appellants

The Appellants seek:

- the annulment of the Contested Decision;

- the reimbursement of the costs incurred by the Appellants in these appeal proceedings; and
- the refund of the appeal fee.

¹ Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency.



Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 25 February 2014 following a substance evaluation of MCCP by the UK Competent Authority.

The Contested Decision requests additional information for MCCP including:

- a. Information on the amounts of carbon chain lengths shorter than C14 that are present at or above 0.1% w/w for all the relevant MCCP product types.
- b. Bioaccumulation in fish: Aqueous and Dietary Exposure (OECD TG 305). Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C14 chlorinated n-alkane with a chlorine content of 50-52% by weight.
- c. Bioaccumulation in fish: Aqueous and Dietary Exposure (OECD TG 305). Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C14 chlorinated n-alkane with a chlorine content of 55-60% by weight.
- d. Aerobic and anaerobic transformation in aquatic sediment systems (EU TM C.24/OECD TG 308). The test substance shall be a C14 chlorinated n-alkane with a chlorine content of 50-52% by weight.
- e. Aerobic and anaerobic transformation in aquatic sediment systems (EU TM C.24/OECD TG 308). The test substance shall be a C14 chlorinated n-alkane with a chlorine content of 55-60% by weight.
- f. Aerobic and anaerobic transformation in aquatic sediment systems (EU TM C.24/OECD TG 308). The test substance shall be a C15 chlorinated n-alkane with a chlorine content of around 51% by weight.
- g. A PBT (Persistent, Bioaccumulative and Toxic) assessment for all relevant constituents of the substance and any transformation product found to be formed in a relevant environmental compartment at any time point, at a concentration of ≥0.1 % w/w.

The Agency observed in the Contested Decision that as several registrants of the same substance are required to provide the same information they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other registrants. If such an agreement is not reached the Agency shall designate one of the registrants and addressees of the Contested Decision to perform the tests on behalf of all of them.

The Appellants contest the Contested Decision on, amongst others, the following grounds.

The Appellants contend that the Contested Decision constitutes an illegal act. The Agency has used the substance evaluation provisions of the REACH Regulation to require testing on surrogate 'test substances' which have not been identified as forming part of commercial MCCP. By requesting data on 'test substances' the Agency has acted in breach of the REACH Regulation and outside its margin of discretion and authority as such testing cannot scientifically address the suspected concern. Given ECHA Guidance and the underlying



intention of the legislator, the Agency also acted in breach of the principles of legitimate expectations and legal certainty.

In addition, the Appellants claim that the Contested Decision constitutes a breach of the principle of proportionality. The data required under the Contested Decision does not have any realistic prospect of providing scientifically reliable or meaningful data on the suspected concern. Therefore, the Contested Decision serves no legal or scientific purposes and is inappropriate and unnecessary.

Furthermore, the Appellants contend that the Contested Decision is illegal as it misinterprets and misapplies the criteria regarding the assessment of the PBT and vPvB (very Persistent and very Bioaccumulative) properties of UVCBs as set out in, amongst others, Annex XIII of the REACH Regulation.

The Appellants also claim that the Contested Decision has been adopted in breach of legal requirements regarding animal welfare by, amongst others, prioritising the need for an expedient assessment of a substance under the REACH substance evaluation procedure above the need to ensure that animal testing is undertaken as a last resort. In addition, the Agency required studies that will serve no useful purpose and, as such, are wasteful of animal life.

Moreover, the Appellants contend that the Contested Decision has been adopted in breach of the legal principles requiring a stepwise approach to testing as the Agency has failed to assess the relevance of the data being requested under the Contested Decision vis-à-vis addressing the suspected concern. The Contested Decision has also been adopted in breach of the principles of good administration and equal treatment as well as the requirement for the Agency to state reasons.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

http://echa.europa.eu/web/quest/regulations/appeals

The CoRAP list of substances is available here:

Link to CoRAP