

EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL ENVIRONMENT DIRECTORATE-GENERAL

Directors General

Brussels, ENTR/G1/EGJ/kp D(2011)

European Chemicals Agency Attn. Mr. Geert Dancet (Executive Director) Annankatu 18, P.O. Box 400 F-00121 Helsinki, Finland

Subject: Request to ECHA to prepare an Annex XV dossier on 1,4-Dichlorobenzene under Regulation 1907/2006 REACH

Dear Mr. Dancet,

1,4 Dichlorobenzene is classified as Carcinogen Category 3, R40 (Carcinogen Cat 2, H351 under CLP). The risk assessment pursuant to Regulation 793/93, has been performed by France and completed in 2004¹ and a strategy for limiting the risks² in accordance with Regulation (EEC) 793/93 was indicated.

The Scientific Committee on Toxicity, Eco-toxicity and the Environment (SCTEE) was consulted and issued an opinion³ with respect to the risk evaluations carried out. In its opinion SCTEE confirmed the need for limiting the risks for human health. In accordance with Article 11(2) of Regulation 793/93 the results of the risk evaluation and the recommended strategy for limiting the risks have been adopted at Community level and published by the Commission⁴.

Commission Communication 2008/C34/01 on the results of the risk evaluation and the risk reduction strategies for several substances, including 1,4 dichlorobenzene (EC No. 203-400-5), indicated for 1,4 Dichlorobenzene the need for specific measures to limit the risks to consumers and workers. For consumers the concerns relate to carcinogenicity as a consequence of inhalation exposure arising from use of moth repellents, air fresheners and toilet blocks. The concerns for workers relate to general systemic toxicity, carcinogenicity and reproductive toxicity as a consequence of inhalation and dermal exposure arising from manufacture and use (intermediate, formulation of products containing the substance and production of grinding wheels) and concerns for ocular and nasal irritation as a consequence of exposure to vapours arising during use of formulation of products containing the substance and production in grinding wheels.

² FR RRS: ES/19b/2006, 10th RRS Meeting

Official Journal of the European Union, 7.2.2008, (2008/C 34/21)

¹ EU Risk Assessment Report on 1,4 DCB, European Chemicals Bureau, Existing substances, Volume 48

SCTEE: Opinion expressed at the 19th CSTEE plenary meeting, Brussels, 9 November 2000

Concerns regarding consumer exposure resulted in the recommendation to consider introducing Community-level marketing and use restrictions for the use of the substance in air-fresheners, moth-repellents and toilet blocks.

Art. 69(1) of Regulation EC 1907/2006 empowers the European Commission to ask the European Chemicals Agency to prepare an Annex XV restriction dossier for those substances for which it considers that their manufacture, placing on the market or use on their own, in a mixture or in an article, poses a risk to human health or to the environment that is not adequately controlled and needs to be addressed.

Considering that new or updated information has become available on the hazards, socioeconomic impact⁵ and market situation of 1,4 DCB, including registration dossiers presented before December 2010, ECHA is requested to prepare Annex XV restriction dossier as foreseen in Art 69(1) of REACH, taking into account the current state of knowledge.

In the preparation of the above-mentioned Annex XV dossier, ECHA should address in particular the evidence and relevance of any new information in the scientific literature. Furthermore it should address the impact of possible changes in consumer and worker exposure as a consequence of decline in the use (and consequent reduction in the amount of the substance placed on the market). Both the exposure of the consumer at home and in public toilets as well as the exposure of professionals storing, transporting and handling the substance and of professionals managing and cleaning public toilets should be considered. The extent by which appropriate risk management is achieved by existing worker protection legislation will be duly taken into account.

According to Article 69(3) of Regulation EC 1907/2006, within 12 months after the receipt of this request from the Commission, ECHA should communicate its conclusion to the Commission and if the dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

Yours sincerely,

DG Enterprise and Industry

Socio-economic evaluation arising from a proposal for Risk reduction measures related to restrictions on 1.4 DCB, Final Report, RPA