

Director General

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Mr Geert DANCET
Executive Director
ECHA - European Chemical Agency
Annankatu 18
P.O. Box 400
SF - 00121 Helsinki (Finland)

18 July 2011

Dear Mr Dancet,

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I am writing to follow-up on an issue already raised in the Directors Contact Group which is of major concern to the Chemical industry.

The ECHA Guidance on Intermediates Version 2, published in December 2010, has major socio-economic consequences for the chemicals industry, notably for companies in fine and specialty chemicals of which many are SMEs. We were very surprised by the publication in December as it did not reflect the long discussions and input given by industry and other stakeholders in the Partner's Expert Group.

Let me draw your attention to the specific problem of "Strictly Controlled Conditions" (SCC). In contrast to the draft Guidance of October 2010 the final version does not give the possibility to use available health and environment data of the substance to conclude on the necessary level of control to meet the requirements of SCC. For example, even regulatory binding occupational limits cannot be used to demonstrate SCC.

This rigid approach has serious consequences for our companies, as the only options to comply are far-reaching modifications of the installations and equipment or a full registration dossier irrespective of the hazard of the substance. We consider the Guidance disproportionate, totally ignoring technical reality and not contributing to the protection of health and the environment. Not to talk about the implications for animal testing!

The definition of intermediates as interpreted in the Guidance is another problem. The Chemical industry disagrees with the interpretation of the definition of intermediates as it goes beyond the scope of the Regulation. Legal opinions supporting our position have been published.

As the ECHA Guidance on Intermediates (December 2010) has tremendous consequences for the chemical industry without adding to the protection of health and the environment, I ask you to revise the Guidance in the spirit of the practicality and workability of previous draft versions.

I stand ready to discuss this at your earliest convenience.

Yours sincerely

Hubert Mandery

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