

**From:** Wolfgang Dekant <dekant@toxi.uni-wuerzburg.de>  
**Sent:** 06 December 2012 15:24  
**To:** SANCO SC ADMINISTRATION  
**Subject:** Re: Participation in the 23rd Risk Assessment Committee (RAC) meeting of the European Chemicals Agency (ECHA)  
**Attachments:** Brief-ECHA.pdf

Please find attached my response to the bwlo mentioned letter.

wd

Am 04.12.12 18:05, schrieb [SANCO-SC-ADMINISTRATION@ec.europa.eu](mailto:SANCO-SC-ADMINISTRATION@ec.europa.eu):

Dear Prof. Bridges,  
Dear Prof. Dekant,

Please find attached a letter signed by our Head of Unit, Mr Tapani PIHA, on the above-referred subject.

Annex :

The original will be sent by post today.

Kind regards,

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*Secretariat of Scientific Committees*

**European Commission**

Health and Consumers Directorate-General  
Risk Assessment Unit  
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Würzburg, 05.12.2012

European Commission  
Health and Consumers Directorate-General  
1049 Brussels  
Attn Mr. Tapani PIHA  
By e-mail

**Subject: My participation in the 23rd Risk Assessment Committee (RAC)  
Meeting of the European Chemicals Agency (ECHA) as expert invited  
by a stakeholder**

Dear Mr. Piha,

I am writing in response to your letter of December 4, 2012, where you request a detailed declaration on my involvement in the 23<sup>rd</sup> RAC meeting of ECHA as an expert nominated by a stakeholder.

In late spring of 2012, I have been asked by the stakeholder, the European Council on Plasticizers and Intermediates (ECPI), to specifically submit a critique of the draft assessment report on di-isononyl phthalate and di-isodecyl phthalate (DINP/DIDP) developed by ECHA. The critique was developed for input into the public consultation process on DINP/DIDP in the summer of 2012. I was selected by ECPI due to my significant experience in risk assessment of chemicals and my familiarity with the toxicology and human exposures to phthalates.

I have analyzed the ECHA report according to generally accepted principles of data analysis in toxicology by a weight of evidence approach and identified several issues in the draft document. The exposure assessment by ECHA contains a misinterpretation of data from the two key studies (selected by ECHA) for exposure assessment to DINP/DIDP in children. In addition, my analysis of the toxicity database on DINP/DIDP resulted in points of departure for risk assessment of DINP and DIDP different from those derived by ECHA. The points of departure for risk assessment derived in my analysis are in agreement with those derived by the US-CPSC and the Australian Government from the same dataset. My analysis also came to the same conclusions regarding NOAELs for DINP/DIDP as proposed by the former CSTEE and by the former ECB. Detailed justifications for my conclusions have been submitted to ECHA in the public consultation process and are available on their website. The sponsor of the

analysis is clearly indicated on the 1<sup>st</sup> page of the submitted document. My participation in the RAC meeting was intended for discussion of the issues identified in my review with RAC members. ECPI has not interfered with my conclusions.

EPCI has paid my normal hourly consulting fee for the time required to evaluate the ECHA report, the available scientific literature, and the preparation of the reports. EPCI also has committed to cover economy class air travel and accommodation to attend the RAC meeting.

Obviously, I will declare this consulting activity if phthalates or other chemicals with EPCI interest should be discussed in SCHER in the future and will not participate in such discussions. As you are aware from the minutes of recent SCHER meetings, I have mainly been involved in the development of opinions regarding metals such as mercury or general issues of risk assessment. These activities have no relation to the issues addressed in the specific consulting assignment discussed above. SCHER also had no requests for opinions on issues connected to ECPI (based on my present knowledge). Thus, there was no reason to declare this activity as a conflict of interest in SCHER or SCENHIR meetings.

Please do not hesitate to contact me if you have questions. You may call my office number at +49-931-201-48449 or my cell phone at +49-173-8551041.

Sincerely,

Prof. Dr. Wolfgang Dekant