

[REDACTED]

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**From:** PIHA Tapani (SANCO)  
**Sent:** 21 January 2014 17:57  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** FW: Your request for disclosure  
**Attachments:** RESPONSE FROM PROFESSOR BRIDGES TO SUGGESTIONS OF A CONFLICT OF INTERESTS REGARDING THE DEVELOPMENT OF THE OPINION ON THE USE OF DIETHYLHEXYLPHthalate IN MEDICAL DEVICES.odt

Info.

**From:** [j.bridges@surrey.ac.uk](mailto:j.bridges@surrey.ac.uk) [<mailto:j.bridges@surrey.ac.uk>]  
**Sent:** Tuesday, January 21, 2014 5:03 PM  
**To:** PIHA Tapani (SANCO)  
**Subject:** Your request for disclosure

Dear Mr Piha,

I am responding to the e-mail from [REDACTED]. I am happy for the correspondence to be disclosed to anyone provided the note I have attached is part of the file. I note that in the internal correspondence there is a reference made to the fact that I should not be part of the BPA WG. This was never mentioned to me and was clearly not conveyed either to the chair of the WG or to the new secretariat.

The issue of independence of scientists is in danger of undermining the future quality of the risk assessments required by DG SANCO. I hope it will consider again how to balance expertise and independence appropriately.

Yours sincerely

Professor Jim Bridges

**RESPONSE FROM PROFESSOR BRIDGES TO SUGGESTIONS OF A CONFLICT OF INTERESTS  
REGARDING THE DEVELOPMENT OF THE OPINION ON THE USE OF DIETHYLHEXYLPHTHALATE IN  
MEDICAL DEVICES.**

**To whom it may concern**

**1. The science**

The suggested conflict of interest arises because, while a member of the WG on the use of Diethyl hexylphthalate (DEHP) in medical devices, I was asked to provide an expert risk assessment for Exxon Ltd on the risk assessment of Di-isononylphthalate (DINP) in children toys. This I did using the objective weight of evidence approach which I developed with the SCENIHR.

It is vital to the understanding of possible conflicts to recognise that there are many phthalates and that the higher molecular weight phthalates have rather different properties from the lower MW phthalates such as DEHP. The two issues (as identified in my letter of December the 5<sup>th</sup>) that I was asked to address in regard to DINP were in particular:

- the relevance of the lead effect found in animals, spongiosis hepatitis, to humans. NB This effect has no link to an endocrine disruption mechanism.
- the use of mouthing data to identify the likely exposure levels.

It should be noted that spongiosis hepatitis is not an effect observed with DEHP and that oral extraction of DINP by children from the mouthing of toys has very little relevance to medical devices which in any case do not use DINP to any significant extent.

**2. The time course of events.**

I joined the WG on DEHP in medical devices primarily because I had been involved in research on DEHP in the past and was a member of the previous WG on this topic (therefore was familiar with a number of the issues). At the time of my joining the WG I had not been approached by Exxon. Once I was approached I mentioned at the next WG that there might be a possible perception of conflict of interest because of other activities but as I was unclear at that point of exactly what was involved I would keep the WG informed. At the meeting of the WG on the 3<sup>rd</sup> of December I informed the members that I could no longer play a substantial role in the WG activities because of the possible perceived conflict of interest. On the 4<sup>th</sup> of December I had an e-mail from the temporary head of unit asking for clarification of my position which I did on the 5<sup>th</sup> of December. This was acknowledged on the 10<sup>th</sup> of December. I decided to take no further part in the activities on the WG and formally resigned by e-mail of the 20<sup>th</sup> Of December. It must be recognised that, at the point at which I resigned the work of the WG was at a very early stage, there was no new text, only an outline of possible section headings and literature to be followed up. Consequently I had no influence on the development of the Opinion nor have I commented on it since.

**3. BPA**

There is no link between BPA and DINP that could be considered as a conflict of interest. In reality because of the stabbing of my wife and I in Barbados in January 2013 and the consequent effects on

our health I played only a minimal part in the development of the BPA opinion and have not sought to influence it since.

**4. The letter from the Commission services in regard to the conflict**

No attempt was made to discuss the situation as perceived by the Commission services with me. I was not aware of any of the internal correspondence of DG SANCO that I have now been shown and even the formal letter to me wasn't received until March at which time it was pointless to reply.

**Professor Jim Bridges January 21<sup>st</sup> 2014**