



## **Scientific Committee on Emerging and Newly Identified Health Risks**

### **SCENIHR**

#### **4<sup>th</sup> meeting of the Working Group on DEHP**

**Venue: rue Breydel 4, meeting room 02/17A**

**Meeting date: 3 Dec. 2012, starting at 10:00**

### **Minutes**

#### **1. WELCOME AND APOLOGIES**

The Chair welcomed the participants and announced the apologies.

#### **2. ADOPTION OF THE AGENDA**

Adopted with the addition of a point (No. 5) on the discussion of the general approach in light of the paper presented by a member of the WG.

#### **3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA**

One member participates in the ISO and CEN technical committees dealing the biological evaluation of the medical devices. The Chair participated in an ECHA meeting on behalf of CEFIC (plastic's industry) who covered his travel. This meeting was specifically on phthalates (DINP and DIDP). Therefore, the Chairs feels that it would be appropriate for him to resign as a chair of this WG. Another member accepted to be the chair and yet another to be the rapporteur.

#### **4. DISCUSSION OF THE RESULTS OF THE CALL FOR EXPERTS**

Some experts were identified for inclusion in the WG.

#### **5. DISCUSSION OF THE LITERATURE SEARCH RESULTS**

One member presented an analysis of the papers to be considered in details. Another member alerted the WG about the work by John Hess and

his publications on RBC storage and transfusion which will need special attention:

[http://www.ncbi.nlm.nih.gov/pubmed?term=\(Hess%5BAuthor%5D\)%20AND%20%233](http://www.ncbi.nlm.nih.gov/pubmed?term=(Hess%5BAuthor%5D)%20AND%20%233)

In addition, the same member tabled two papers to be scanned and distributed via electronic means. The secretariat clarified that all the papers received as a result of the literature search performed by BRE and the ones received in response to the Call for Information have been sent out in 6 consecutive messages during the last three days.

## **6. DISCUSSION OF THE GENERAL APPROACH TO BE USED IN THE OPINION**

The lead effect (for TDI determination) should be relevant to the vulnerable group under consideration.

The definition of the uncertainties is a main issue. The default factor of 10x10 may be appropriate.

The exposure estimate is to be done in terms of the nature of the device in terms of its DEHP content (for longer term use of the medical device) or surface area (for the short term exposure to the medical device) as well as other sources of exposure including multiple devices and for young children mouthing of DEHP objects

## **7. DISCUSSION ON THE DRAFT OPINION**

The Table of Contents of the previous opinion could serve as a template for the new text.

Start each chapter with a summary of the results of the previous opinion (the conclusions).

## **8. ANY OTHER BUSINESS – NEXT MEETINGS**

28 Jan. 2013 and 22 March 2013