



EUROPEAN COMMISSION  
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection  
European Centre for the Validation of Alternative Methods (ECVAM)

ECVAM  
SCIENTIFIC  
ADVISORY  
COMMITTEE  
(ESAC)

## Specific Conflicts of Interest ESAC 34

### 1 Background

4 ESAC members announced specific conflicts of interest concerning three of the agenda points to be discussed during ESAC 34. It was agreed that the ESAC members with specific conflicts of interest should summarise these and provide this information to the ESAC Secretariat to allow archiving this information on the ESAC-CIRCA electronic document repository. Moreover, this information will allow to come to transparent decisions on whether or not the raised conflicts of interest are to be judged prejudicial with respect to (1) participating in the requested project (e.g. review) and (2) ESAC decision making on the project (e.g. endorsement of ESAC Opinion).

### 2 Specific conflicts of interests as communicated to the Secretariat

The information forwarded is reproduced below and summarised in table 1.

#### David Basketter:

*"Given my role as chairman of the Skin Sensitisation Validation Management Team and that approximately three years ago I gave paid advice to Givaudan regarding the progression of sensitisation methods towards validation, it seems appropriate for me to stand down as ESAC chair for the item on skin sensitisation which relates directly to these matters."*

#### Nathalie Alepee:

*"Sensitisation: (a) Working for one of the companies that have submitted a test method currently undergoing ECVAM Prevalidation (MUSST assay). (b) Member of the VMG of the ECVAM-coordinated prevalidation study of three skin sensitisation tests. Eye irritation (PS for CM/FL): Working for company that is lead laboratory in another in vitro eye irritation assay."*

#### Kristin Schirmer:

*"We obtained the cell lines on which the KeratinoSens assay is based by [redacted] from Givaudan and are currently establishing this assay in our lab to identify reactive organic industrial chemicals."*

#### Rodger Curren:

*"I have several potential conflicts of interest with agenda items for ESAC 34, and I would like to formally announce them for the record."*

1). Agenda item 5 (skin sensitization) – My laboratory participated in the ring trial organized by Givaudan.

2). Agenda item 6 (performance standards) – I wrote the BRD for the Cytosensor microphysiometer method and my laboratory conducts fee for service activities with the instrument.

3) Agenda item 8 (3T3 NRU assay) – My laboratory was a participating laboratory in the ECVAM sponsored study of cytotoxicity and acute systemic toxicity, and it provides this assay on a fee for service basis."

**Table 1:** Specific conflicts of interest (COI) as mentioned by ESAC members during ESAC 34 and conclusions on whether or not these COI are considered prejudicial.

ESAC member	<b>A</b> ESAC review of four assays for skin sensitisation testing (agenda point 5)	<b>B</b> Definition and review of Performance Standards for two eye irritation assays (agenda point 6)	<b>C</b> ESAC review of the follow up study concerning the PC of the 3T3 NRU assay (agenda point 8)	Judged prejudicial by ECVAM with respect to participating in requested project <b>AND</b> for subsequent ESAC decision making (i.e. endorsement of opinion)?
<b>1</b> David Basketter	<b>A1:</b>  (a) Chair of ECVAM VMG coordinating the Prevalidation study  (b) Acted as paid consultant to Givaudan (rel. to Keratinosens) 2 years ago	none	none	<b>A1(a) YES</b> <b>A1(b) YES</b>
<b>2</b> Nathalie Alépée	<b>A2:</b>  (a) Working for one of the companies that have submitted a test method currently undergoing ECVAM Prevalidation (MUSST assay).  (b) Member of the VMG.	<b>B2:</b>  (a) Working for company that is lead laboratory in another in vitro eye irritation assay.	none	<b>A2(a) YES</b> <b>A2(b) YES</b> <b>B2(a) NO</b>
<b>3</b> Rodger Curren	<b>A3:</b>  Involved as testing laboratory in the Keratinosens ring trial	<b>B3:</b>  (a) involved as contractor in the retrospective validation of the CM test method.  (b) providing CRO services using the CM method	<b>C3:</b>  (a) representing one of the laboratories that was involved in generating additional data to assess method robustness (abbreviated protocol)  (b) providing CRO services using the 3T3 NRU assay	<b>A3 YES</b>  <b>B3(a) NO</b> <b>B3(b) NO</b> <b>C3(a) YES</b> <b>C3(b) YES</b>
<b>4</b> Kristin Schirmer	<b>A4:</b>  Obtained for laboratory of employing organisation those cell lines on which the Keratinosens assay is based on directly from Givaudan. The cells are used for a chemical reactivity assay in another context (not for sensitisation testing).	none	none	<b>A4 NO</b>