Brussels, 27th June 2011

EPAA/DG JRC ADME Workshop
"Potential for further integration of toxicokinetic modelling into the prediction of in vivo dose-response curves without animal experiments"

Date & Location: 13-14 October 2011,
EC JRC, Institute for Health and Consumer Protection, In Vitro Methods Unit (ECVAM), Ispra, Italy

Dear Sir/Madam,

We would like to enquire about your availability for a joint EPAA/DG JRC ADME workshop in Ispra on 13th and 14th October 2011, focusing on the evaluation of potential and limitations of in silico toxicokinetic models.

This workshop is a follow-up to the first EPAA workshop on this topic, in November 2008 in Dusseldorf, which has been successful in identifying the challenges and bringing together the relevant stakeholders. Its results have recently been published in "Toxicology in vitro"[1].

The main objective of this 2nd workshop is to identify both scientific and methodological gaps and to generate recommendations on how to address them. The outcome will inform test developers, toxicologists, safety assessors, regulators and research program officers on the priorities to focus on how to progress this to a new integrated risk assessment paradigm.

As a follow up on the recent expert report coordinated by ECVAM for the Commission "Alternative (non-animal) methods for cosmetics testing: current status and future prospects—2010" (Adler et al, 2011[2]) the session will also assess how to address the need for full replacement methods to animal testing as required by the EU Regulation on cosmetics. This report (available soon on DG SANCO website and electronically published in Archives of Toxicology, in June also as paper copy) highlights that alternatives in Toxicokinetics will play a key role.

Metabolism was originally considered to be responsible for inactivation or detoxification of foreign compounds in the human body. However, in the current regulatory requirements for chemicals and cosmetics, toxicokinetic and metabolism evaluations are not part of the main base-set of tests. Yet, it has become increasingly clear that metabolism-mediated toxicity is an important issue in regulatory toxicology.

With a view to replacing animal testing, particularly in cosmetics, in vitro/in silico methods for establishing the toxicokinetics and metabolism of unknown chemicals will provide essential information for risk assessment. They may provide the decisive part of the information used for further decision making. Kinetic parameters will be vital for gathering the most valuable toxicity data and for designing the related test strategies.

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[1] Schroeder K et al. (2011) Report from the EPAA workshop: In vitro ADME in safety testing used by EPAA industry sectors. *Tox. in Vitro* 25 (2011) 589–604 (Pubmed link) http://www.ncbi.nlm.nih.gov/pubmed/21167275

[2] Adler et al. (2011) Alternative (Non-Animal) Methods for Cosmetics Testing: Current Status and Future Prospects – 2010 (Pubmed link) http://www.ncbi.nlm.nih.gov/pubmed/21533817

Please review the practical information below and let us know as soon as possible at Iwona.Wilk-Zasadna@ec.europa.eu if you intend to participate. In case of a positive response, an official invitation will be sent swiftly.
Together with your confirmation of interest to attend, please send the answers to the questions on the "Background document" in attachment, as well as your willingness to present these in a 10 minutes flash presentation.

We look forward to hearing from you and hope to welcome you on 12 October.

For the Scientific Committee,

Yours sincerely

Cornelis Brekelmans
Adviser
European Commission
DG Enterprise and Industry

Gianni Dal Negro
Director
Laboratory Animal Science Worldwide
GlaxoSmithKline R&D Limited

WORKSHOP INFORMATION

"Potential for further integration of toxicokinetic modelling into the prediction of in vivo dose-response curves without animal experiments"

DATE, VENUE AND PROGRAMME

13-14 October 2011 (arrival of participants on the evening of 12 October).
EC JRC, Institute for Health and Consumer Protection, In Vitro Methods Unit (ECVAM), Ispra, Italy.
The meeting is by invitation only, and we would be very pleased if you would agree to participate and contribute to these important discussions.
For further information on the Programme and for Background info please see Annex.

REGISTRATION

Please indicate your availability/intention to participate by 15 June at the latest, via email to Iwona.Wilk-Zasadna@ec.europa.eu with a copy to Jonathan Crozier communication@epaaind.eu.

SCIENTIFIC COMMITTEE

The Scientific organizing committee consist of:

-Sofia Batista-Leite (EC JRC, IHCP, ECVAM, Italy),
-Jos Bessems (RIVM, Netherlands),
-Sandra Coecke, (EC JRC, IHCP, ECVAM, Italy),
-Walter Diembeck (Beiersdorf),
-Liesbeth Geraets (RIVM, the Netherlands),
-Joachim Kreysa (EC JRC, IHCP, ECVAM, Italy),
-Gaby Küesters (EPAA)
-George Loizou (HSL, UK),
-Olavi Pelkonen (Univ. Oulu, Finland),
-Iwona Wilk-Zasadna (EC JRC, IHCP, ECVAM, Italy)