



ALTEX

ALTERNATIVES TO ANIMAL EXPERIMENTATION

Food for thought ...

Melvin E. Andersen, Harvey J. Clewell, III, Paul L. Carmichael, and Kim Boekelheide:

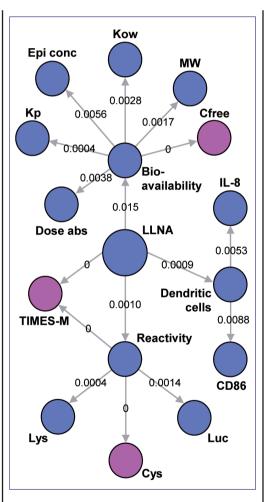
Can case study approaches speed implementation of the NRC report: "Toxicity Testing in the 21st Century: A Vision and a Strategy?"

Joanna Jaworska,
Artsiom Harol, Petra S. Kern,
and G. Frank Gerberick:
Integrating non-animal test
information into an
adaptive testing strategy
- skin sensitization proof of
concept case

t⁴ report:

Thomas Hartung, Bas J. Blaauboer, Sieto Bosgra, et al.:

An expert consortium review of the EC-commissioned report "Alternative (non-animal) methods for cosmetics testing: current status and future prospects – 2010"



Rolando Perdomo-Morales, Zenia Pardo-Ruiz, Ingo Spreitzer, Alicia Lagarto, and Thomas Montag:

Monocyte activation test (MAT) reliably detects pyrogens in parenteral formulations of human serum albumin

t⁴ workshop report:

Ellen K. Silbergeld, Elizabeth Q. Contreras, Thomas Hartung, et al.:

Nanotoxicology:

"The end of the beginning"

- Signs on the roadmap
to a strategy for assuring
the safe application
and use of nanomaterials

Letters Corners News Calendar of events





Dear readers,

In this year's third issue I am proud to announce the new impact factor of ALTEX for 2010 of 4.4. A big thank you to all authors of the past two years for their valuable contributions, which have been recognized widely in the field, and to our production team for giving the manuscripts their final polish. On this note, congratulations to Philipp Kuegler and colleagues, winners of the ALTEX prize 2011.

Motivated by the increasing public interest in the ethics of the animal-human relationship we are relaunching ALTEXethik under the name of TIERethik this fall. TIERethik will be published twice a year (see the News).

It was a pleasure to meet or catch up with many of you at the World Congress in Montreal. As a documentation of the Congress we are currently producing the Proceedings of WC8, which will be sent on DVD to all participants of the meeting and will also be available online. The Proceedings are sponsored by the Doerenkamp-Zbinden Foundation. We congratulate CAAT, the Center for Alternatives to Animal Testing at Johns Hopkins University on its 30th anniversary, which was celebrated as part of the WC8 Get-Together Party, and the winners of the many prizes awarded at the closing ceremony.

The Food for thought ... article, written by **Mel Andersen** and colleagues, explores the promise of case study approaches to implement the vision of "Toxicity Testing in the 21st Century". They propose that a handful of known toxicants with known mechanisms of toxicity be used to develop *in vitro* assays that detect perturbations of these pathways of toxicity by other substances. Combining this approach with mapping the human toxome (see Hartung and McBride, *ALTEX* 28, 83-93) could accelerate the implementation of Tox-21c by building on current technologies and integrating new technologies as they develop.

Joanna Jaworska and colleagues take us step by step through a Bayesian Network Integrated Testing Strategy developed for assessing skin sensitization. The paper demonstrates the adaptability of the strategy to different model chemicals depending on what testing data is available, and how the strategy can be used to assess the potential contribution of data generated from a new test to decide whether it should be performed.

A t⁴ report compiled by **Thomas Hartung** from comments invited from 17 experts evaluates "Alternative (Non-Animal) Methods for Cosmetics Testing: Current Status and Future Prospects – 2010," an EC-commissioned report (Adler et al., *Arch Toxicol* 85, 367-485). With constructive criticism and new pointers, the conclusion by Adler and 54 co-authors that there will be no validated alternative methods for full replacement of repeated dose toxicity testing, carcinogenicity and reproductive toxicity testing of cosmetics by 2013 is

confirmed. Although toxicokinetics and skin sensitization will also likely not be fully replaced by 2013, this goal is likely to be reached within this decade. The state of the science is irrefutably clear, so now the decision whether the Commission will introduce a proposal to postpone or lift the 2013 ban of the above animal tests is down to pure politics. An impact assessment considering the effects of the ban on all stakeholders (animal welfare, consumers, competitiveness, SME's, employment and trade) and asking their opinion on three action options is being compiled to aid this decision (see the News).

The monocyte activation test (MAT) has now been evaluated for its applicability to human serum albumin testing by **Rolando Perdomo-Morales** et al. by comparing results of the rabbit pyrogen test, and two versions of the Limulus Amoebocyte Lysate (LAL) test with two versions of the MAT in 16 HSA preparations. They find that the MAT is more reliable than the LAL for HSA testing, as β -glucan contaminations from the production process do not interfere with its detection of endotoxin, and argue that this may also be the case for other therapeutic proteins.

Two letters in this issue report on the sustained lack of medical relevance of a set of successful animal experiments after 17 years and on a survey of the use of alternatives and the option of conscientious objection in education at German universities.

We welcome ecopa, the European consensus-platform for alternatives, together with the 14 national platforms, which will submit a regular corner in ALTEX.

In further news, we summarize the recent ECHA report, which analyses the current use of animals for testing for REACH purposes and warns that animal tests are being waived by companies without sufficient justification, and the Bateson report, which analyses the use of non-human primates in UK research and admonishes some of the scientists for making unrealistic promises of clinical applicability of their research and for shirking their responsibility to provide information on their results and publish negative data to avoid duplication. The US FDA has approved an *in vitro* test for batch release of a botulinum toxin product – a very promising development that will relieve much severe animal suffering. Further prizes and calls for grant applications are also included.

Hoping you enjoy this issue of ALTEX,

Sonja von Aulock Editor in Chief, ALTEX

U2 ALTEX 28, 3/11



The full program will be available mid-September at http://cms.uni-konstanz.de/leist/caat-europe and www.caat.jhsph.edu

Registration:

- Free for CAAT Sponsors and Associates, federal agencies, students and NGO representatives; € 100 after September 28
- € 300 early registration; € 500 after September 28 Contact: caat-eu@uni-konstanz.de



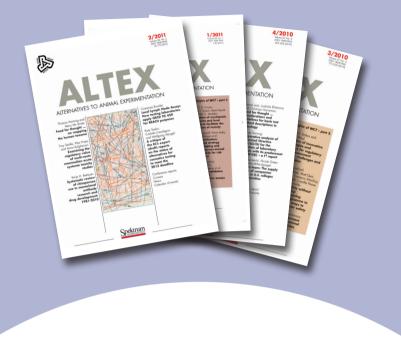
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