

## Dear readers,

Validation is a key theme in this issue of ALTEX. The concept of “validation” is problematic, as it is used within toxicology to describe different versions of the same thing, i.e. in house validation, inter-laboratory validation, formal validation, and because, although it is mandatory for *in vitro* tests, animal tests that have been used for decades and are considered the “gold standards” by which *in vitro* tests are measured, have not been formally validated themselves. Furthermore, validation neither ensures acceptance by regulatory bodies, nor does acceptance of a method as “valid” require formal validation studies.

In their invited contribution to the “Food for thought ...” series, Neil Wilcox and Alan Goldberg explain the history and process of formal test method validation in the US and the EU and discuss why current major challenges to toxicology, i.e. the Cosmetics Directive, REACH and Tox21c, require a new, more flexible approach to validation.

Kevin Crofton and co-authors compile guidance criteria for the development of high throughput screening methods for developmental neurotoxicity. Following these criteria from the start should lead to the efficient generation of data that will enable evaluation and comparison of predictive capacity and efficiency, finally converging in method validation.

Erwin van Vliet focuses on the practical challenges posed by the Tox-21c vision and details what needs to be done to enable maturation, implementation and validation of the various promising technologies required to achieve the envisaged paradigm shift.

The article by Silke Bitz in issue 2/10 on safety testing of botulinum neurotoxin (botox) has initiated a lively discussion in the Comment section. Because botox is a toxin that is injected into the skin, it is necessarily classified as a drug and safety testing entails LD<sub>50</sub> tests on mice for each batch. But as botox is also widely used for cosmetic applications, the contributors to the discussion argue whether the ban on animal experiments for cosmetics should also be extended to botox and how alternative tests may be implemented. A number of animal welfare organizations are currently running awareness campaigns on this issue.

In our third and last installment of Highlights from WC7 Mark Cronin et al. describe how local QSAR models can be used to predict toxicity using the examples of teratogenicity and skin sensitization, Gavin Maxwell and colleagues present the Colipa strategy for developing alternative methods for

skin sensitization and Phillippe Vanparys and coauthors report on the successful prevalidation of three promising cell transformation assays.

About 25,000 files were submitted by the first of three REACH registration deadlines in November 2010. These are hazardous and high production volume substances likely to trigger new safety testing. The exact number of substances registered will be announced by the European Chemicals Agency (ECHA) when all files have been analysed (cp. Rovida and Hartung, ALTEX 3/09; comment and reply 4/09). The declaration that EPA and ECHA have agreed to cooperate and share data on chemical risk assessment is promising in this regard as it should obviate duplicate testing on both sides of the Atlantic. Also in the News we report on approval milestones for two alternative assays, a number of prizes as well as the plans of Swiss drug companies to promote the 3Rs.

The regular newsletters submitted by ASCCT, CAAT/CAAT-Europe, ICCVAM/NICEATM and IIVS bring you up to date on their current activities and future plans in our new “Corners” section.

Since the first issue of ALTEX was published in 1984 (then called “*Alternativen zu Tierexperimenten*”) Irène Hagemann has contributed to and edited our journal. She took all technical novelties in her stride – fax, internet, e-mails and new versions of word processing programs – and approached them with interest and openness. Her relationship with Gotthard Teutsch ensured that ALTEX not only catered to the natural sciences but also included philosophical studies on the animal-human relationship. Now, at 85 years of age, Irène has decided to retire. The ALTEX teams thanks her warmly and wishes her many more years to enjoy reading ALTEX.

Please note that the registration and abstract submission (deadline 10 April) for the 8<sup>th</sup> World Congress on Alternatives and Animal Use in the Life Sciences is now open.

Hoping you enjoy reading this issue of ALTEX.



Sonja von Aulock  
Editor in chief, ALTEX