

## Dear readers,

Upon going to press we received the news that India has announced a ban on animal experiments for cosmetics and their ingredients, aligning India's policy with that of the European Union. Testing strategies for new cosmetic products must be agreed by the Central Drug Standards Control Organisation and conform to the Bureau of Indian Standards' non-animal standards. A violation of this ban can lead to up to ten years imprisonment, a hefty fine, or both. Imported cosmetic products are not affected by the ban.

In the USA the lasted Gallup poll (http://www.gallup.com) performed in May 2013 showed a 9% decline in the number of Americans that find medical testing on animals morally acceptable since 2001 (from 65 to 56%). Being among the largest changes documented, this issue may gain increasing weight in politics in future and feed into upcoming legislative changes, such as the modernization of the Toxic Substances Control Act, for which reform bills recently have been introduced before the Senate.

In this vein, the U. S. Environmental Protection Agency has just issued new guidance on the assessment of pesticides aiming to reduce use of animals which can be as high as 10,000 animals per substance; the NIH has announced plans to retire 90% of its chimpanzees from research; and a recent article by Maffini et al. in *Comprehensive Reviews in Food Science and Food Safety* criticizing the U. S. Food and Drug Administration's program to assess the safety of food additives may trigger a substantial update of this program that will hopefully also follow the 3R principle and promote the use of current and future alternatives to animal experiments.

In the current issue of ALTEX, Thomas Hartung asks in his Food for thought ... why 95% of drug candidates fail to prove safety and efficacy in clinical trials. It seems that preclinical studies, both animal and *in vitro* studies, are often of little relevance or poor quality, building up hopes that are later dashed, sometimes even causing unforeseen serious side effects. He gives examples of studies that have tried and failed to reproduce seminal preclinical data and of studies that show how commonly laboratory cell lines are contaminated by mycoplasma or overgrown by other cell lines.

Miriam Jacobs et al. discuss the testing of endocrine active substances and make recommendations for the incorporation of metabolic enzyme systems and toxicokinetic aspects to improve the predictivity of *in vitro* assays for identifying endocrine active substances and endocrine disruptors. Louise Saldutti et al. report on a t<sup>4</sup> workshop focusing on *in vitro* testicular toxicity tests and describe both the state of the art and the opportunities offered these tests, especially by bioengineering techniques.

Karin Dreisig and colleagues challenge a batch of in vitro assays for developmental toxicity and embryotoxicity with conazole fungicides and find an overall good correlation with results from animal studies and Barae Jomaa et al. challenge in vitro thyroid and pituitary cell proliferation assays with thyroid-active compounds and compare their results with results from animal studies. They find that the current in vitro assays do not cover all relevant modes of action and recommend the development of further in vitro assays, but they find that the tests may be helpful to predict in vivo effects on relative heart weight. Sebastian Polak harnesses two in silico platforms for pharmacokinetics prediction and cardiac effect prediction to model the in vivo effects of quinidine on humans based on in vitro data. He demonstrates that this prediction correlates well with data from clinical studies on the drugs' effects and may be suitable for application as a drug safety evaluation procedure.

A workshop report, five corners, and more current news round off this issue.

Wishing you a good summer break and a productive meeting in Linz this September,

Sonja von Aulock Editor in chief, ALTEX

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