Food for thought …
Katy Taylor, Wolfgang Stengel, Carlotta Casalegno, and David Andrew:
Experiences of the REACH testing proposals system to reduce animal testing

Food for thought …
Lena Smirnova, Helena T. Hogberg, Marcel Leist, and Thomas Hartung:
Developmental neurotoxicity – Challenges in the 21st century and in vitro opportunities

P. Charukeshi Chandrasekera and John J. Pippin:
Of rodents and men: Species-specific glucose regulation and type 2 diabetes research

Jean Knight and Costanza Rovida:
Safety evaluations under the proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal use and cost estimates

Vanessa Ashall and Kate Millar:
Endpoint matrix: a conceptual tool to promote consideration of the multiple dimensions of humane endpoints

Comments
Workshop reports
Calendar of events
Corners
News
Dear readers,

It seems that some developments in the field of alternatives to animal experiments are going in diametrically opposed directions right now. The image on this issue’s cover indicates how the proposed Safe Cosmetics and Personal Care Products Act would greatly increase animal testing for cosmetics ingredients in the US if it is passed, despite the EU finally banning all animal testing on cosmetic ingredients and products last year. In the article this image illustrates, Jean Knight and Costanza Rovida have explored recent numbers of animals used for cosmetics testing and different possible scenarios that could arise depending on the interpretation of the bill. A different bill, as reported in the News section, would completely ban animal testing on cosmetic ingredients in the US. If this is passed instead it would likely lead to a worldwide end of animal experiments for cosmetic ingredients. In our News we also report that India and the state of São Paulo in Brazil have decided to follow the lead of the EU, Israel, and Norway to ban animal testing for cosmetics.

Another issue in which developments are going in different directions is experiments on primates. In the US two dozen companies, now including Merck & Co., have agreed to stop experiments on chimpanzees following last year’s announcement that the NIH will retire 90% of its chimpanzees. No great apes have been used for experimental purposes in the European Union since 1999 and the number of prosimians and non-human primates used for scientific purposes has decreased there as well (see ALTEX 31, 101). However, the German Federal Administrative Court has passed its final ruling permitting contentious macaque experiments in Bremen after a long legal battle. The wider implications of the court’s decision have led to the German Animal Welfare Federation pulling out of all ethics committees and filing a complaint against the German state, as explained by Ruhdel and colleagues in their Comment.

Katy Taylor and colleagues provide Food for Thought … on the experience of the European Coalition to End Animal Experiments (ECEAE) with third party commenting on REACH testing proposals. Although the legislation clearly states that animal experiments are to be performed only as “a last resort” and although it provides the possibility for third parties to identify existing data or alternative methods within a short timeframe, the enormous efforts of ECEAE to prepare such comments have generally been unsuccessful as the European Chemicals Agency (ECHA) leaves the decision to the registrant, although the registrant may choose to retract the testing proposal on the basis of the third party comments. In a Comment, Taylor also reports on a survey on the level of EU member state contribution to alternative methods as demanded by Directive 2010/63/EU, noting that numerous states provide no contribution or are unable or unwilling to provide information on their efforts.

Just before the DNT4 meeting in May, Lena Smirnova et al. contribute Food for Thought … discussing opportunities and challenges of developmental neurotoxicity testing. The increase in neurodevelopmental disorders may be related to environmental chemicals but to date only 150 substances have been tested in the rat assay that is very expensive both in terms of animal lives and money, and only five have been identified as DNToxicants. Therefore, there is a need for high-throughput in vitro strategies. Complementing this article, a Workshop Report by Crofton et al. describes efforts to produce a roadmap for developmental neurotoxicity testing for regulatory purposes.

The article by Chandrasekera and Pippin explores the value of diabetes research in rodent models by comparing data on glucose regulation in rodents and humans at all levels from gene expression to whole organisms. They conclude that the vast differences between the species at each level strongly support the development of models based on human cells and tissues.

In their Short Communication, Ashall and Millar introduce us to the concept of “unpredictable endpoints”, i.e., illnesses or accidents that are unrelated to experimental treatment, which they argue should be considered next to scientific and justifiable endpoints in the design of animal experiments to allow one to determine when animals should be taken out of experiments.

Corners and News as well as the Calendar with all 3Rs related events for the next months round off this issue and keep you up to date with new developments.

For your convenience the references for each article now include digital object identifier (DOI) links. These are active links in the online versions of our manuscripts, posted on http://www.altex-edition.org, that lead you straight to the full pdfs of the referenced articles, although you will, of course, still have to pay to view articles from many other journals.

Please note that early registration for the 9th World Congress on Alternatives and Animal Use in the Life Sciences ends on May 31; authors will be notified of acceptance of their abstracts by May 15.

Hoping you enjoy reading this issue of ALTEX,

Sonja von Aulock
Editor in chief, ALTEX
II. Predictive Toxicology – Updates, Computational Approaches, Risk Assessment and Advances in Specific Assessments

Coordinators: Nathalie Alépée, L’Oreal, Aulnay-sous-Bois, France

1. Pathway analysis in toxicology (e.g. aCOP)
2. Systems biology
3. Updates on research programs around the world (e.g. Tox21, The Cancer Project & FPP program, ARCH-Top.)
4. Exposure
5. Topicality
6. Repeated dose toxicity
7. Skin sensitization
8. Reproductive and developmental toxicology
9. Computational modeling and chem-informatics
10. Genotoxicity / Carcinogenicity
11. Inhalation toxicity
12. Ecotoxicology
13. Computational modeling and chem-informatics
14. Risk assessment (e.g. chemicals, drugs, cosmetics, medical devices, nanomaterials, metagenomics, biologics etc.)
15. Discussion session: Model based testing strategies and decision making

III. 3Rs in academia and education

Coordinators: Gilly Griffin, CCAC, Ottawa, Canada

1. 3Rs in academia and education, training programs and anticipated tools
2. Funding agencies and funding programs (e.g. Horizon 2020)
3. Innovative teaching and training tools
4. Discussion session: Montreal Declaration

IV. Communication, dissemination and data sharing

1. Information requirements on project proposals (e.g. Horizon2020)
2. Scientific reporting standards (in vivo and in vitro)
3. Dataset deposition / non-technical summaries (2010/63)
4. Information systems and databases
5. Intellectual property rights

V. Efficacy and safety testing of drugs and biologicals

Coordinators: Belén Torres, Albé, North Cheeth, IL, USA – IQ consortium
1. In vitro disease models
2. Use of stem cells in screening
3. Human biomarker
4. Alloplasmic, distribution, metabolism and excretion
5. Ethical Biobanks
6. Discussion session: Pros and cons on animal models

VI. Animal Relevance

Coordinators: Tuula Heinonen, FCM, Tampere, Finland
Theresa Hartung, CARAT-Bodywerke, Meppen, Germany
Matthias Dankanich, CAAE, Karlsruhe, Germany
1. In vivo disease models
2. Use of stem cells in screening
3. Human biomarker
4. Alloplasmic, distribution, metabolism and excretion
5. Ethical Biobanks
6. Discussion session: Pros and cons on animal models

VII. Ethics

Coordinators: Kay Taylor, BMBF, London, UK
1. Ethical and normative aspects of human-based approaches
2. Ethics of using animals
3. Ethical evaluation
4. Distances evaluation
5. Benefit evaluation

VIII. Refinement and welfare

Coordinators: Joanne Zarits, CAFÉ, Baltimore, MD, USA
Thierry Decelle, Sesan, Pasteur, Marsilly, France
Queck, Present, NCCL, London, UK
3. Non-human primates
4. Best practices wellness approaches / case studies
5. Humanine principles in experimental techniques
6. Avoidance of severe suffering
7. Culture of care
8. Transgene

IX. Global cooperation, regulatory acceptance and standardization

Coordinators: Chantara Esake, SeCApE, Switzerland
Miguel Ferrada, San Francisco, Spain
Mitsugi Kojima, JAICRM, Tokyo, Japan
Gergely Tóth, EURL, ECAMA, London, UK
1. Activity updates from international scientific societies
2. Animal welfare implementation across the world
3. Activity updates from international validation centres
4. Novel approaches to validation
5. Regulatory acceptance of alternatives
6. Breaking down barriers and promoting international cooperation on 3Rs
7. X. Frees communications

Coordinators: Horst Spemann, FU Berlin, Germany
1. Ethical and normative aspects of human-based approaches
2. Use of stem cells in screening
3. Ethical Biobanks
4. Discussion session: Montreal Declaration

The abstracts will be published in an international scientific journal focused on 3Rs with impact factor.
A computational

Food for thought …

Anne marie Vinggaard,
Altex
and Karine Audouze:

for regulatory purposes

QSAR-based approa

Kristine Kongsbak,
Domenico Gadaleta,
emilio Benfenati, and

Refinement
for predicting the

ettore Novellino,
orazio Nicolotti:

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