

Dear readers,

this is the second issue of *ALTEX* published entirely in English. Most of *ALTEX* Supplement 1/2003 is made up of an extensive review of alternatives to safety testing in animals for regulatory purposes and was written on behalf of the Swiss Foundation FFVFF by the internationally established expert Jane Huggins from the University of Michigan. In addition, Brigitte Rusche, head of the Academy for Animal Welfare of the "Deutscher Tierschutzbund", critically assesses the current perception of the 3R concept from the perspective of animal welfare organisations. These articles cover two topics that stand at the centre of the conflict between the science and ethics of animal experimentation in the year 2003.

When the Swiss foundation FFVFF decided five years ago to focus on progress in developing alternatives to toxicological testing in animals for regulatory purposes, the US government and the EU Commission had not yet passed the current legislation that requires additional safety testing of existing chemicals in Europe and in the USA in order to assess the environmental hazards posed by the chemicals. This initiative was pushed by environmentalists on either side of the Atlantic who demanded toxicity testing of all existing chemicals irrespective of any financial or ethical considerations and funding by government and/or industry. Very conservative calculations of this task indicate that applying the currently established regulatory tests in animals to 30.000 existing chemicals, for which data on hazardous properties are needed for a realistic risk assessment, 12 million laboratory animals will have to be sacrificed over a 20 year period in Europe. This is neither acceptable from the ethical/animal welfare perspective nor for financial reasons from the view of the tax payer or industry. To meet the needs of environmentalists, animal welfare organisations, industry and the tax payer, the EU Commission put forward the REACH (Registration, Evaluation and Accreditation of Chemicals) Program in May of this year. The REACH Program suggests that all basic testing of chemicals be done using non-animal/*in vitro* alternative tests. Experts of the EU Commission and the 15 member states are currently evaluating whether this is a realistic scenario, since so far only four *in vitro* toxicity tests have been accepted by the EU Commission and the OECD.

For the reasons given, politicians, industry and regulators favour the use of *in vitro* toxicity tests over animal tests, but they only provide very limited financial support for the development and validation of such tests. To stimulate the discussion and to provide a realistic perspective, Jane Huggins has compiled an extensive review and evaluation of alternative tests that have already been accepted for regulatory purposes or which hold promise for this purpose in the near future. Jane Huggins' position paper on the current status of alternatives to the use of animals is most welcome, since it will facilitate focus of research funding by the EU Commission and EU member states on the most promising methods in this specific area of the biomedical sciences.

Apart from the testing of chemicals, safety testing of cosmetics and cosmetic ingredients has been heavily criticised during the past 20 years on both sides of the Atlantic and quite recently

also by consumers and the government in Japan. After a series of unsuccessful attempts during the past 20 years to ban safety testing of cosmetics in animals – both for finished products and ingredients – the European Parliament and the EU Commission passed the 7th Amendment of the EU Cosmetics Directive 76/768/EEG earlier this year, which calls for a step-wise ban of testing in animals over a 10 year period. Again, as a first step, the EU Commission and the 15 member states will have to establish an inventory of non-animal test methods that have been scientifically validated and can be used for regulatory purposes. In a second step, funding will have to be provided for the development and validation of the most promising alternative tests. For the reasons stated, Jane Huggins' position paper is also most welcome to those involved in implementing the new EU cosmetics directive, since it provides a scientific basis for regulatory decisions of the safety testing of cosmetics without the use of animals.

Thus, Jane Huggins' position paper is one of the few reviews that will help allow members of parliaments, industry and regulatory agencies at the international level to set realistic deadlines for implementing the new non-animal tests in the areas of safety testing of chemicals and of cosmetics in particular.

Brigitte Rusche critically evaluates how the 3R concept of Bill Russel and Rex Burch has been implemented in the reality of conducting animal experiments according to EU Directive 86/609/EEC for the protection of animals used for experiments and other scientific purposes. The author clearly indicates that from the animal welfare point of view all animal experiments should be replaced immediately by non-animal methods. In the real world in Europe in the year 2003, laboratory animals are more fortunate than their ancestors a few generations ago, since the most prominent funding agencies in EU member states agreed in 2000 to accept that animals are fellow companions. Consequently, they insist that all scientists in Europe implement the 3R concept and provide education for young scientists in conducting animal experiments humanely according to the 3R principle. From an animal welfare perspective this development is most welcome. On the other hand, our colleagues, who contribute their time and knowledge as members of the local commission for animal experiments in Germany, may not share my positive view from their experience, since to date no animal experiment could be prevented in Germany for purely ethical reasons.

On the other hand, there is the good news that in the year 2003 faculty positions for C3 professors will be devoted in Germany to the 3R principle according to Russel and Burch at two universities in Konstanz and Hannover. In fact, the two positions were advertised in *ALTEX* earlier this year.

I hope you will enjoy the special *ALTEX* supplement devoted to alternatives for regulatory testing and implementing the 3R concept in Europe.

With best wishes



Horst Spielmann