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Project

Analysis of EU-legislation in terms of consistency and state-of-the-art regarding the implementation of the 3Rs in the data requirements to identify potential for further improvement

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3R reduce refine replace

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Analysis of EU-legislation in terms of consistency and state-of-the-art regarding the implementation of the 3Rs in the data requirements to identify potential for further improvement

According to the recent EU statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union, 8.7 % of a total of 12 million animals that were used in the acquisition period were used in toxicological tests or other tests for risk assessment[1].

For reasons of product and food safety, chemicals, active substances and new products like biocidal products or plant protection products have to undergo risk assessment prior to marketing authorisation. The lion's share of tests to assess possible risks to human health is still based on testing on animals.

At the same time the EU Directive on the protection of animals used for scientific purposes[2] requires that, wherever alternative methods recognised by Union legislation are available, they have to be used instead of animal tests. However, this principle is implemented neither consistently nor to its full extent.

The Animal Welfare Academy of the German Animal Welfare Federation used this as an occasion to analyse and compare data requirements of relevant EU legislation that requires animal testing for risk assessment of chemicals, active substances and products in terms of consistency and to see if accepted alternative methods are considered.

After a thorough analysis of the EU Chemicals Regulation REACH, Biocidal Products Regulation, Plant Protection Products Regulation and corresponding Regulations on data requirements for the authorisation of plant protection products, EU Test Methods Regulation 440/2008/EC and EU Novel Foods Regulation the following results were obtained:

Some of the more than 40 internationally accepted test methods that are currently available are not considered. In addition, there a considerable number of inconsistencies could be identified within the analysed legislation and when comparing legislation to legislation. Design and structure of the data requirements are non-uniform and often confusing; this is also true when comparing the terminologies that were used. Considerable disparities in terms of wording end references to rules for adaptation and waiving criteria became obvious as well. This failure in adapting the data requirements to the state of the art in toxicity testing and the plethora of different provisions and requirements for diverse product ranges causes a large number of unnecessary or duplicated animal tests, confusion for competent authorities, applicants and manufacturers, additional costs and a flood of information that is almost impossible to handle.

To resolve the problems that were identified and to help to ameliorate the consideration of animal welfare a list of recommendations was drafted. These recommendations will hopefully also lead to an economisation of costs and to a harmonisation of data requirements for risk assessment at EU level und thus will help to facilitate the implementation of these measures and to increase consumer safety:

The European Commission has to act immediately and has to eliminate those animal tests from the data requirements that can be replaced by accepted alternative methods. To prevent inconsistencies and to promote the swift implementation of the 3Rs principle it is recommended to set up a central organ or institution that is responsible for the design and update of data requirements. One of the responsibilities of this central organ should also be drafting and/or

updating a harmonized strategy to address the aforementioned issues. It is also highly recommended to agree on best practice rules regarding if and in what time frame 3Rs methods that were adopted by the OECD as a Test Guideline have to be accepted and incorporated in EU legislation.

The results of the analysis and the list of recommendations that were drafted were published and will also be presented to the European Commission and other relevant institutions. With this project the Animal Welfare Academy aimed would like to contribute to drastically reduce the number of animals and the distress that is inflicted upon them. It is also designed to lead to an economisation of costs and to a harmonisation of data requirements for risk assessment at EU level und thus will help to facilitate the implementation of these measures and to increase consumer safety.

The final project report has just been published in ALTEX 29 3/12 and can be found under the following link:

http://www.altex.ch/resources/altex_2012_3_302_332_Wagner11.pdf

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[1] Report from the Commission to the Council and the European Parliament - Sixth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union SEC(2010) 1107 (COM(2010) 511 final)

[2] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

Project Manager

Roman Kolar, Dipl. Biol.

Born in 1964, studied Biology at the Ruhr-University Bochum. Since 1994 he has been working as scientific officer for the German Animal Welfare Federation (Deutscher Tierschutzbund). He is Deputy Director of the Animal Welfare Academy, the scientific affiliation to the German Animal Welfare Federation. He is member of several national and international committees and bodies that deal with issues of animal experimentation and alternatives and author of numerous publications in the field of animal experimentation and alternatives.

Research Team

Kristina Wagner, Dipl. Biol.

Born in 1981, studied Biology with focus on human biology, neurobiology and cell biology at the Technical University and Ludwig-Maximilians-University in Munich. Since 2009, she works as a scientific officer at the Animal Welfare Academy of the German Animal Welfare Federation. Subject areas of her work include alternatives and replacement of regulatory animal testing: OECD Test Guidelines, EU Chemicals Regulation REACH, biocidal products, plant protection products, nanotechnology, marine biotoxins and food safety.

Bettina Fach, Dipl. Biol.

Born in 1978, Bettina Fach studied Biology at the University of Ulm and University of Potsdam. She focused on limnology, ecophysiology of micro-algae, nature conservation and environmental chemistry. After finishing her degree, she turned to the University of Rostock to work as a scientific staff member in the research group for Applied Ecology. Currently, she works as a project associate at the Animal Welfare Academy.

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