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Risiken erkennen – Gesundheit schützen

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## **New EC chemicals legislation: Animal welfare and consumer protection are reconcilable!**

A dramatic increase in animal experiments can be avoided by using new test strategies

**According to the Federal Institute for Risk Assessment (BfR), the new European chemicals legislation leads to a noticeable improvement in health protection (cf. Press release 18/2003). This improvement is not necessarily linked to considerably higher numbers of experimental animals as feared by various sides. BfR determined this in a new study. BfR President Professor Dr. Dr. Andreas Hensel commented, "All the same, the precondition is that the alternative methods to animals experiments currently undergoing development and testing are rapidly recognised and used internationally".**

European chemicals legislation is to be completely revamped. The core is the draft submitted last October by the European Commission. This new concept summed up under the acronym REACH stands for the Registration, Evaluation and Authorisation of Chemicals.

Up to now, only newly developed chemicals were subject to a notification procedure requiring an assessment of the health risk. The risk assessment of the so-called existing substances, which are far larger in terms of volume, that have been on the market for decades has been dragging its feet for the last 20 years. According to the proposal of the European Commission, a uniform procedure for all chemicals is to be introduced in future. Health and consumer protection are to be improved by means of a compulsory programme for hazard identification, risk assessment and risk reduction. In particular chemicals, which are considered to be carcinogenic mutagenic or reprotoxic from the toxicological angle, are in future to undergo a European authorisation procedure.

Industry criticises the fact that REACH would generate costs amounting to billions. The gaps in knowledge about the 20,000 to 30,000 chemicals which have been marketed for decades but which have not been sufficiently investigated would have to be closed by toxicological animal experiments. Animal protection groups are apprehensive that the REACH programme will generate an absolutely enormous number of animal experiments. This would be unacceptable on ethical grounds.

Scientists at BfR, who are responsible in Germany for the toxicological assessment of chemicals, have estimated the volume of animal experiments involved in the execution of REACH. They calculated the number of experimental animals required if the chemicals, including existing chemicals, are to be examined in line with the toxicological methods recommended by REACH. The result: under these preconditions 45 million experimental animals could be needed within the next 15 years.

In a second calculation the BfR scientists estimated the number of experimental animals that would be needed if new, including many methods and concepts requiring no experimental animals, were to be used without reducing the level of health protection.

According to the scientists only 7.5 million animals (mainly rats) would be needed over the same period. This must be seen against the backdrop that the health risks of all important chemicals on the market would be assessed. After the expiry of the 15 years, the need for these animals would fall dramatically in both cases.

According to this study, the development of these new toxicological methods will have a decisive impact on the future need for animal experiments. Unfortunately, the methods are frequently not recognised internationally. Their acceptance and recognition will, therefore, exert a considerable influence on the future need for animal experiments within the REACH concept.

80% of the 7.5 million experimental animals estimated in the second calculation are needed in order to throw light on the health risks of chemical exposure during pregnancy and infant development. That's why the European Union, under the current 6th Framework Programme, is supporting the development of methods involving no animal experiments for the assessment of these risks in a multidisciplinary, multinational project with 35 partner institutions in which BfR is also involved.

The number of animal experiments can only be minimised if the often bureaucratic, formal regulation of the testing of substances requiring specific animal experiments can be replaced by a more flexible strategy. At the same time, computeraided expert systems and laboratory methods involving no animal experiments must be further developed and validated in experiments. Here, BfR scientists are of the opinion that additional support funds are needed. If they are not validated, the use of alternative and new test methods for the scientific assessment of health risks is not acceptable!

The English language BfR study will be published in the journal Archives of Toxicology (Volume 78) under the title "Animal testing and alternative approaches for the human health risk assessment under the proposed new European chemicals regulation". It can already be accessed now in the online offering of the Springer Publishing House Heidelberg.

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### Press releases

- [Planned European Chemical System means progress for consumer health protection 18/2003, 2003-07-22](#)