

Intelligent testing strategy for the assessment of chemicals drastically reduces number of animal tests

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Chemical substances can endanger human reproduction and children during pregnancy. The new European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) demands extensive animal testing over the next years. According to estimations, over 80 percent of these animal experiments are needed for the study of risks for reproduction and unborn children. Together with international experts within the Organisation for Economic Co-operation and Development (OECD) chemicals programme, the Federal Institute for Risk Assessment (BfR) has assessed these risks in a “chemical category approach” for 61 structurally similar chemicals. The chemicals in question are surfactants, which are predominantly used in cleaning agents and detergents. A few studies were sufficient in order to scientifically assess the potential hazards of all 61 chemicals. Over 95 percent of the projected animal experiments could thus be avoided. The application of chemical category approaches substitutes a large number of animal experiments and therefore constitutes an alternative to these. The approach does not question the strict safety requirements for the assessment of risks of consumer products.

In 2004, BfR published a study estimating the number of animal experiments that would be necessary for the new chemical regulation which was still in the planning phase at the time and is now in force. For the first time, BfR reported on the large number of animal experiments that would be needed in order to detect the hazards of so-called reproductive toxicity – i.e. hazards to fertility and the healthy development of children. According BfR estimations at the time, this would require over 80 percent of animal experiments under REACH (<http://www.springerlink.com/content/4mmmftrfu04f7fe/>).

The Institute is working to reduce this number whilst ensuring scientific chemical assessments of the risks for mother and child. BfR has thus advocates animal-free testing and a revision of international testing guidelines within an OECD programme. Furthermore, the toxicological assessment process of chemicals itself bears potential for reducing the number of animal experiments. OECD leads worldwide in developing procedural requirements for chemical category approaches as well as using computer modelling to study structure-activity relationships.

The current risk assessment of alkyl sulphates as well as alkyl and olefin sulphonates for human health was carried out in the OECD High Production Volume Chemicals Programme under German direction. The 61 chemicals assessed in this context are used in household cleaning agents, laundry detergents and cosmetics. These so-called anionic surfactants have effects similar to soap. They were summed up in one chemical category because their physicochemically and known toxicological properties as well as their transformation during metabolism are very similar in humans. After the chemical category approach had been carried out, experts agreed that the assessment of reproductive toxicity of these chemicals would require a single 2-generation study on rats (so-called OECD TG 416) and a few smaller studies in order to adequately estimate the safety risk for consumer products for all 61 chemicals. The case study showed that the chemical category approach substituted comprehensive individual testing on reproductive toxicity for 60 out of 61 chemicals. Experiments on less than 5,000 animals thus allowed studies with a potential number of 150,000 rats, especially young animals, to be avoided. These numbers illustrate the enormous savings potential of animal experiments if chemical categories are evaluated instead of individual chemicals by themselves.

The assessments of 61 chemicals and the complete report on the chemical category which was completed within the OECD chemical assessment programme are available on the OECD Environment Directorate website under the heading “Co-operation on the Investigation of Existing Chemicals” as “Initial hazard assessment of the Alkyl Sulfates, Alkane Sulfonates and α Olefin Sulfonates Category” (<http://www.oecd.org/env/existingchemicals/siars>). These internationally usable publications of chemical assessments recognised by experts in major industrialised nations help to avoid redundant work worldwide and could also be used for other regulations.