

Implications of the proposal for a new chemicals legislation

- REACH system -

for

animal testing

The proposal for a new chemicals legislation (REACH system) adopted on 29 October 2003 by the European Commission¹ seeks to balance animal welfare considerations against the potentially serious threats to human health and the environment from insufficiently tested chemicals. It does not simply propose to test or re-test chemicals, but rather to collect all available information. Testing should only be necessary where further information on the dangerous properties is needed to assess the risks of the substances. The aim of the REACH proposal is to eventually achieve sustainable development in the field of chemicals policy. As such, it aims not only to protect human health but also the environment including wild animals.

The REACH proposal was triggered by the general lack of information about the dangerous properties of chemicals on the market. More than 99 % of the entire tonnage of such chemicals, the so-called “existing” substances, are not subject to the standard information requirements prescribed for “new” substances. New substances are chemicals placed on the market for the first time in 1981 or later, existing substances have been placed on the market already before that date. The testing requirements for new substances give us an appropriate picture about their dangerous properties, and thus their risks can be reliably assessed by considering the exposure of man and the environment to such substances. For existing substances, however, knowledge about the dangerous properties is generally very limited. Therefore, it is nearly impossible to know whether such substances can represent serious risks for humans and the environment, including for animals. Therefore a substantially improved knowledge of the dangerous properties of such chemicals is necessary.

To remedy this knowledge gap the REACH proposal suggests making available any information about the dangerous properties (or hazards) of substances. The following elements have been developed with a view to keeping animal testing to a minimum:

- Existing information on the toxicity and ecotoxicity of substances, including epidemiological studies, results from computer calculations and international sources, will be taken into account before deciding whether additional testing is necessary;
- The general testing requirements incorporate exposure-driven testing where appropriate, in order to limit testing;
- Substances which are similar may be grouped, where appropriate, in order to minimise testing;

¹ <http://europa.eu.int/comm/environment/chemicals/whitepaper.htm>

- For substances produced/imported in quantities between 1 - 10 tonnes per year and per manufacturer/importer, testing should generally be limited to *in vitro* methods;
- For the testing of higher production volume chemicals tailor-made testing programmes will be developed under the control of authorities;
- The development of new alternative testing methods using fewer or no animals will be fostered under the Community Framework Programme for Research and Technological Development. Researchers submitting suitable projects for such methods will be funded from the Programme.

Unfortunately, today the hazards of chemicals can only be insufficiently determined with the available *in vitro* test methods (using no test animals). This is noted in a report published by the European Centre for the Validation of Alternative methods, ECVAM². Use of *in vitro* methods alone would therefore underestimate the hazards of chemicals which could be harmful to human health and the environment.

It is important to note that for chemicals testing the animal species most often used are mice, rats, fish and daphniae. Guinea pigs or rabbits are used to a lesser extent. Other animals such as dogs are used only in extremely rare circumstances.

The European Commission advocates a more intense development of alternative test methods. Thus, in the Fifth Framework Programme for Research and Technological Development (1998 - 2002), it funded more than 43 research projects for *in vitro* methods with approximately € 65 million. In the current Sixth Framework Programme researchers are more than ever requested to submit suitable projects. This should eventually lead to internationally validated alternative test methods providing results which are unanimously acceptable to regulators.

The Joint Research Centre of the European Commission has a lead role within an OECD-Initiative for the validation of computer methods. As more of these so-called QSAR methods become available for estimating the hazards of chemicals, the number of animal experiments will further decrease.

Finally the Commission has started the revision of Directive 86/609/EEC on the protection of laboratory animals, in order to improve the protection of such animals.

² A. P. Worth, M. Balls (ed.), alternative (Non-animal) Methods for chemicals test Ing: Current status and Future Prospects – A report prepared by ECVAM and the ECVAM Working Group on chemicals. ATLA 30, Supplement 1, July 2002.