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Human Health Risk Assessment of Animal Testing Under Chemical-Regulation.

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ABSTRACT

A realistic scenario based on an in-depth discussion of potential toxicological developments and an optimized "tailor-made" testing strategy shows that to meet the goals of the REACH policy, animal numbers may be significantly reduced below 10 million if industry would use in-house data from toxicity testing, which are confidential, if non-animal tests would be used, and if information from quantitative structure activity relationships (QSARs) would be applied in substance-tailored testing schemes. The procedures for evaluating the reproductive toxicity of chemicals have the strongest impact on the total number of animals bred for testing under REACHE. We are assuming both an active collaboration with our colleagues in industry and substantial funding of the development and validation of advanced non-animal methods by the EU Commission, specifically in reproductive and developmental toxicity. Our traditional animal-based approaches to toxicity testing into ones which protect human health and the environment without requiring animal testing.

Keywords: Risk assessments, Animal experiment, REACHE.

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INTRODUCTION

The development of the new Chemicals Policy has been driven by the unsuccessful current approach for risk management of the majority of existing chemicals. Driven by the aim to finalize the risk assessments for all existing chemicals within 12-15 years. The need for obtaining data on the hazardous properties of these chemicals became urgent. During the last two decades of the current legislation, industry did not comprehensively test their chemical products. Partly because lack of incentives for hazard identification based on appropriate toxicological testing. The health hazard and risk assessment of all existing chemicals not tested in the past will inevitably need "retrospective" toxicological testing ECORA (The European Consensus Platform on alternatives) a non govt. initiative by scientists has raised Substantial increase in laboratory animal testing may result from the proposed regulation. (EUCOM 2003d).

Specific details of the recently proposed REACH system:

- The registration of Chemical
- The evaluation Procedures with in industry and the development of tailored testing
- The regulation of the authorization of high risk substances (in carcinogenic, mutagenic & reprotoxic chemicals)
- The establishment of a new European agency for the regulation of chemicals and several stake holder committees.

Testing Methods for health hazards

Although acceptance is mandatory for OECD member Countries only their results are accepted by regulators throughout the world. The tests cover the most important health end points for safe handling of chemicals and products.

Over several decades in vivo tests have been developed are refined with the aim to detect the characterize inherent toxic properties and their dose effect relationships. The White paper (EUCOM 2001) as well as the European Parliament (EU Parliament 2001) suggest that in the first place testing should be restricted to *in-vitro* tests a general agreement on appropriately radiated in vitro tests is still missing (Worth & Balls 2002). Toxicological endpoints & hazards to be assessed therefore discuss these prospective and challenges

RESULT

However general multi stage toxicological processes are difficult to stimulate (Rosencrantz 2003) when drafting REACH. The EU Commission carefully noted the limitations of QSAR.

DISCUSSION

To need for mammalation testing under the REACH programme on solid ground. We are providing an estimate of the testing requirements based on our personal experiences during the past 20 years in the national regulatory agency in Germany i.e. responsible for the risk assessment. A chemical all animals that we have to be a bred to live under experimental conditions to allow for any toxicological evaluation based on the REACH regulation. Either as exposed animals or as controls. This report is written from a EU prospective. It is also relevant for regulatory toxicological outside EU. All chemicals assessed by regulators standards of the EU.

- Collection, evaluation & verification of Publishes (Q) SAR rules in order to support the development of new systems (Hulyebos et al.2003, Rosencrantz 2003).
- Discussing the above mentioned (Q) SAR systems for the purpose of REACH (Hulyebos & Posthumous 2003, Rosencrantz 2003).
- Amendment of existing (Q) SAR Prediction systems such as DEREK based on regulatory experience in the assessment of new chemicals in the EV (Gener et.al 2003).

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