Dermatotoxicological and other Safety Testing Methods without Animals - State November 2013

Introduction

Ban of cosmetics testing in animals and roadmap for toxicity testing in the EU "Horizon 2020" Program

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The deadline for the 2013 marketing ban in the Cosmetics Directive/Regulation has entered into force on 11 March 2013. This completes a 20 year long process on phasing out animal testing for the purpose of cosmetic safety assessment. Promising progress has been made in advancing alternative methods to animal testing over the last years, but full replacement is not yet possible and will not be possible for some time. The Commission nevertheless believes that the most appropriate way forward is to let the marketing ban enter into force and to turn the challenges that the 2013 marketing ban is posing into an opportunity, in particular by

- ensuring a coherent implementation of the 2013 marketing ban and monitoring its impacts;
- continuing the support for research, development and validation of new alternative methods for human safety testing; and
- making alternative methods an integral part of the EU's trade agenda and international cooperation.

To successfully meet the requirements of the EU cosmetics ban, the EU DG Research and Innovation (R&I) of the EU Commission has funded research on alternatives for local toxicity testing with 238 Mio €. Due to this effort Europe has internationally taken the lead in toxicology. However, so far only in vitro safety tests for local toxicity have been accepted for regulatory purposes, while advanced non-animal toxicity test for all of the other toxicity endpoints still have to be developed. Therefore, the DG R&I should in the upcoming 5-year program "Horizon 2020" provide sufficient funding for funding to replace all safety tests in animal tests by advanced non-animal toxicity tests.

To meet this challenge, the EU FP7 project AXLR8 has proposed "to accelerate the transition to a toxicity pathway-based paradigm for chemical safety assessment through internationally co-ordinated research and technology development". The proposal is based on a concept proposed by the US Academy of Science in 2007 entitled "Toxicity Testing in the 21st Century", in which they suggested to identify "adverse outcome pathways" (AOPs) in human cells and tissues to develop new toxicity tests. The AOP approach has successfully been applied to replace animal tests for skin irritation by an integrated testing strategy (ITS) based on in vitro tests. The AXLR8 Scientific Committee has, therefore, proposes a "roadmap for toxicity testing under Horizon2020" to the DG R&I of the EU Commission. To implement this proposal in a "public private partnership" (PPP) between EU Commission and industry, annual funding of 50-100 Mio€ will be required to achieve the goal of replacing the "classical toxicity tests in animals" by non-animal tests using human cells and tissues.