

# Comment

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## A FRAME Response to the European Commission Consultation on the *Draft Report on Alternative (Non-animal) Methods for Cosmetics Testing: Current Status and Future Prospects — 2010*<sup>a</sup>

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**Summary** — This response on behalf of FRAME to the European Commission's consultation on the five chapters of the *Draft Report on Alternative (Non-animal) Methods for Cosmetics Testing: Current Status and Future Prospects — 2010*, is via a *Comment* in *ATLA*, rather than via the template supplied by the Commission. This is principally so that a number of general points about cosmetic ingredient testing can be made. It is concluded that the five draft chapters do not provide a credible basis for the Commission's forthcoming report to the European Parliament and the European Council on the five cosmetic ingredient safety issues for which the 7th Amendment to the Cosmetic Directive's ban on animal testing was postponed until 2013. This is mainly because there is insufficient focus in the draft chapters on the specific nature of cosmetic ingredients, their uses, their local effects and metabolism at their sites of application, and, in particular, on whether their possible absorption into the body would be likely to lead to their accumulation in target sites at levels approaching Thresholds of Toxicological Concern. Meanwhile, there continues to be uncertainty about how the provisions of the Cosmetics Directive should be applied, given the requirements of the REACH system and directives concerned with the safety of other chemicals and products.

**Key words:** *alternative methods, animal tests, carcinogenicity, cosmetic ingredients, Cosmetics Directive, in silico, in vitro, REACH system, repeated dose testing, reproductive toxicity, skin sensitisation, toxicokinetics.*

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### Introduction

In July 2010, the European Commission indicated a desire to consult the public on the five chapters of a *Draft Report on Alternative (Non-animal) Methods for Cosmetics Testing: Current Status and Future Prospects — 2010*, in order “to ensure that each chapter correctly reflects the current state of the art and the prospects”. This draft report was prepared by working groups of experts nominated by the various stakeholders and chaired by the Commission's Joint Research Centre (JRC), in order to gain a broad and objective picture of the scientific/technical issues that relate to establishing alternative test methods for the five human

health(-related) effects falling under the 2013 deadline for the marketing ban of the EU Cosmetics Directive. It was also intended that the draft report would contain, where possible, a science-based estimate of the time necessary to achieve full replacement of animal testing for the respective endpoints.

*Directive 76/768/EEC* (the Cosmetics Directive) is a regulatory framework for the placing on the market of cosmetic products, and subsequent amendments and associated directives have aimed to phase out the use of animal testing for these purposes. Besides the complete testing ban, a marketing ban has applied since 11 March 2009, for all human health(-related) effects, with the exception

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<sup>a</sup>The authors gratefully acknowledge their very useful discussions with Professor Horst Spielmann (Department of Biology, Chemistry and Pharmacy, Free University of Berlin, Berlin, Germany) during the preparation of this Comment.