

Teil 1: Konsequenzen eines Vermarktungsverbotes aus verschiedener Sicht

Safety Assessment of Cosmetic Ingredients and Toxicological Testing without or with the minimal use of Animals

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The use of alternatives to animal studies in toxicology is an ethical imperative and is hence strongly recommended by current EU regulations (i.a. REACH), animal testing is avoided whenever possible. With the new EC Cosmetics Directive animal testing of cosmetic ingredients is completely prohibited for acute toxic effects from 2009 and for repeated dose toxicity from 2013 onwards.

These requirements present a great challenge to the chemical and cosmetics industry, since the safety of cosmetic ingredients is of paramount importance and must be ensured. This could be achieved by using intelligent testing strategies and in vitro methods – provided appropriate methods are available.

For several toxic effects in vitro methods have been established and accepted for regulatory use: skin- and eye irritation as well as skin absorption. These methods are used in routine testing of cosmetic ingredients. Among them, the dermal penetration study using human skin preparations (OECD TG 428) has been a valuable tool in generating data for internal exposure and risk assessments. For other – usually more complex – effects, there is still a need for appropriate in vitro methods and testing strategies: skin sensitization, inhalation toxicity, systemic/organ toxicity after repeated exposure, carcinogenicity and reproductive toxicity. Herein, we propose a concern-driven strategy without or with the minimal use of animal testing for that reason. This strategy is based in the following pillars: 1) Definition of the potential concerns for the use of the cosmetic ingredient, 2) Address potential concerns, 3) Consider the completeness and validity of these data to assess the identified concerns and 4) Chose a risk assessment approach accommodating all of the abovementioned information.

Even though, many efforts have been done to develop strategies to assure the safety of cosmetic ingredients, there is still a great demand for appropriate in vitro methods and also some lack of understanding toxic mechanisms in vivo. Since the safety of cosmetic ingredients is the paramount goal, risk assessment of cosmetic ingredients shall foster the development and validation of new in vitro methods as well as testing and assessment strategies to allow the development and safe use of new cosmetic ingredients in the future.

