

Lecture: 7th cosmetics amendment – can all goals be achieved in time?

The incorporation of 3R alternatives in the safety evaluation of cosmetic ingredients by the SCC(NF)P

Marleen Pauwels, Vera Rogiers

Vrije Universiteit Brussel (Brussel) (BE)

e-mail: marleen.pauwels@vub.ac.be

Although animal tests are commonly used by regulatory bodies as the basis for hazard and safety assessments of all types of chemicals, the upcoming testing and marketing ban in the cosmetic field legally imposes urgent substitution for these animal studies by replacement alternatives. At the EU level, the Scientific Committee on Consumer Products or SCCP (formerly called SCCNFP) assesses on a regular basis colourants, preservatives, UV filters, hair dyes and other specific cosmetic ingredients for which suspicion of potential toxicity exists. Therefore it appeared useful to investigate the incorporation of 3R alternatives in the dossiers submitted to this European scientific committee.

To achieve this, we programmed a database in which the contents of 185 SCC(NF)P opinions were systematically loaded and which allowed to search for the occurrence of alternative methods and to perform animal counts.

A first set of results reveals that, when validated, 3R alternative methods appear to smoothly find their way in the submissions to the SCC(NF)P. Examples are the gradual incorporation of the fixed dose procedure, the toxic class method and the up and down procedure in the field of acute toxicity, the introduction of reduction and refinement measures in existing animal protocols in the areas of skin and eye irritation, the transition to the local lymph node assay for skin sensitisation, the standard use of the in vitro mutagenicity/genotoxicity testing battery and the regular occurrence of the 3T3 neutral red uptake phototoxicity test. A subsequent post-validation study on the available data sets, however, showed that several methods still required optimization and further development (e.g. mutagenicity/genotoxicity, skin irritation).

For the major animal-consuming endpoints, namely repeated dose toxicity and reproductive toxicity, as well as for toxicokinetics and carcinogenicity, the studies encountered in the SCCP dossiers appeared to be the classical animal assays as performed for decades. Unfortunately, no replacement alternatives are in the pipeline for these endpoints.

In a separate step, the database was used to compute the numbers of animals that were involved in the data generation for the dossiers submitted to the SCC(NF)P. In a worst case calculation, 21,000 animals are estimated to be used per year.

It is clear that the deadlines of 2009 and 2013 will not be met with regard to the timely development of replacement alternatives for all toxicological endpoints. The SCCP, the Scientific Committee dealing with the safety assessment of cosmetic ingredients at the European level, to date still mainly uses results from animal studies for its safety assessments, although it clearly welcomes the use of alternatives once validated (see also SCCP/1111/07).

Therefore further efforts need to be focused on development, validation, post-validation and more than anything on trust-building in alternative methods. Meanwhile the cosmetic world remains caught in a deadlock created by political influences and unsolvable by the scientific community.

References

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