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EDITORIAL

Is the replacement strategy, as it exists today in the EU for cosmetics, the way forward ?

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During our daily life, we are exposed to a variety of chemical substances and products including cosmetics and their ingredients. When they are brought on the EU market, they must be safe for human health. This safety is traditionally guaranteed through quantitative risk assessment which is not only based on human exposure data, but in particular on testing results derived from experimental animals, assessing both local and whole organism systemic toxicity.

For local and short-term toxicity, the development of 3R (Refinement, Reduction and Replacement)—alternative methods had some important success. A number of toxicological endpoints, including skin corrosion, skin irritation, eye irritation, skin sensitization, phototoxicity, dermal absorption, acute toxicity, and in vitro genotoxicity/mutagenicity testing could be covered, although not all with replacement and stand-alone alternatives (EU 2010). Refinement and reduction are, for example at the basis of the local lymph node assay (LLNA), used for skin sensitization testing; for eye irritation only some screening tests for strong irritants are available. For long-term and systemic toxicity testing, consuming in fact the largest number of experimental animals, nearly no alternatives are available and the time required for their scientific development is a huge question mark.

Exactly here lies the problem!

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In the EU, the cosmetic legislation was made the most stringent one of the world by bringing in a rigid time frame through testing and marketing bans (EU 1976 amended by EU 2003). This political decision has positive and negative sides. Positive is the fact that over the last years the number of efforts, made by all stakeholders involved (academic world, industry, animal welfare, and legislative bodies) substantially improved. Also collaboration towards a common goal gained importance and financial resources in the field became more available. A negative outcome, however, is that this politically driven initiative does not take into account the scientific feasibility of the timely and complex development of alternatives to guarantee human safety. Personally spoken, I see as one of the most limiting factors for further progress in the cosmetic field, the way Europe sticks to replacement methods only. This deliberate choice "kills" reduction and refinement efforts. As such, progress made in the practical application of tiered approaches combining in vitro and in vivo methodology, and of read across and weight of evidence strategies, is ignored to a major extend. This is difficult to accept as these strategies became internationally accepted to come to a more balanced risk assessment and at the same time save animal lives. Also very recently, a panel of European experts reported on the current status and future prospects of non-animal methods for cosmetic testing (Adler et al. 2011, this issue). They concluded that specific timelines were impossible to give for these areas in which most animals are consumed, namely for reproductive toxicity, repeated dose toxicity, carcinogenicity, and toxicokinetics. Interesting to note is that they also concluded that significant advances were made in reducing the number of animals in tests by refinement strategies and by the use of non-animal methods alongside animal tests. From March 2013, however, this is no longer possible.

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