Malmö, 2011-03-09

Regarding

Questions for targeted stakeholder consultation 2013 Implementation date Marketing Ban cosmetics directive.

This answer is on behalf of the Swedish Contact Dermatitis Group.
The text below address the questions generally and especially questions number 2) Impact on animal welfare/environmental impact, and 3), Impact on Consumers, this being the major concern of the group. Magnus Bruze and Cecilia Svedman are both members of the Swedish Contact Dermatitis Group.

The answers need not be kept confidential.

2.1.2. Regarding dermal aspects of toxicology the animals used for testing are rodents, this includes tests for skin irritation and sensitization. It has to be taken into consideration that within toxicology dermal application is sometimes used to study systemic effects of a drug/substance and this is not considered in this answer.
With regard to sensitization, which is the most important aspect to consider, LLNA (Local lymph node assay) is the gold standard to decide on the sensitizing capacity of a substance and for this mice are used. Regarding cross reactivity GPMT (Guinea pig maximisation test) is the test of choice. The in vitro methods developed so far has not been able to give the same information. Thus with a total ban of use of animals the risk assessment will deteriorate.
2.1.3.-2.1.4. Here we would only like to emphasize that even if a substance is used as a cosmetic drug there may well have been risk assessments performed with the substance for another purpose.
2.2.11 It is important to emphasize that cosmetics used for the skin are not only cosmetics used to improve the estethic aspects but within this group falls also moisturizers and protection creams that may have a medical and occupational important purpose. The need for these will most probably not decline.
2.3.1-2.37. The support that has been given and the need that has been outspoken for alternative methods have been important for the development of the in vitro techniques that are described such as cell based assays (MUSST and h-CLAT) and direct peptide reactivity assay (DPRA) but these have not been able to replace the aforementioned techniques so far in the actual risk assessments.
3.1.1. See above no.
3.1.2.-3.1.3 For the EU to be able to adhere to a legislation/ban controls will mean a need for regulatory measurements at regular intervals.

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