

Cosmetics Europe Meeting with European Commission

25/09/2014

Attendance:

- DG TRADE ([**Art. 4.1b**])
- DG SANCO ([**Art. 4.1b**])
- Cosmetics Europe

1) Pilot project on colorants

- Industry noted that they are not interested in increasing the range of authorised colorants in the US.
- The comparison of specifications on a paper basis could be feasible. Industry is ready to provide the specifications set in Annex IV of EU Cosmetics Regulation.
- The pilot project would demand a number of scientists from both sides
- Industry reminded that there were several attempts in the past in the US to establish comprehensive cosmetics legislation but without success.
- In the week of 29 September Cosmetics Europe and PCPC will meet to discuss the objectives of TTIP and will come back to the Commission with their outcome, including the confirmation of whether the pilot project on colorants is of interest for the industry.

2) UV filters

- The set of safety data required by SCCS is for most parts the same as the set required by FDA, except for 'carcinogenicity' and 'toxicokinetics', where the US systematically requires studies.
- These endpoints also need to be addressed in the EU, however, if these endpoints are not in the submissions, the SCCS considers other ways or asks for these data if really needed (in some cases this can be done without specific studies).
- Industry supports the Commission's approach to continue the discussion with the US at expert level on safety assessment of UV filters.
- Industry advised to include former SCCS experts who were rapporteurs of the SCCS opinions on UV filters (such as [**Art. 4.1b**]) into the discussion.
- Industry welcomed the replies (even though negative) by FDA to the applicants for authorisation of UV filters sent recently after more than 10 years of silence.

3) Animal testing

- Industry and Commission agreed that the objective of the negotiations should be to establish a common harmonized framework for safety assessment of cosmetics without the need for animal testing (in the US).
- Industry highlighted that alternative methods are cheaper and more convenient for manufacturers than in-vivo tests.
- Industry pointed out that when the US manufacturers are not sure if an alternative method is sufficient and there is no regulatory guidance, they rather opt for animal testing to demonstrate safety of their products.
- Therefore, the industry and the Commission would like to see from the US, as an outcome of the negotiations, a clear positive statement by the US that whenever there is an alternative

method to animal testing, validated and accepted by OECD, such method should be formally recommended to be used by the US cosmetic manufacturers. Such a statement would incite the manufacturers to opt for alternative methods to animal testing in the US.

3) Good Manufacturing Practices (GMP)

- The Commission highlighted that the US does not have a legal requirement for normal cosmetics GMP (as opposed to OTC). This could be a challenge for some of US industry.
- Industry noted that if the manufacturer follows FDA GMP for pharma he is automatically covered for ISO GMP for cosmetics.
- Industry asked the Commission to remind the US that ICCR jurisdictions agreed to consider the ISO standard as the key reference. All but FDA have said that ISO was the key standard without modifications. In addition, the US was involved in the production of the ISO GMP for cosmetics.
- The Commission will further discuss this issue with the US.