

SCIENTIFIC COMMITTEE ON CONSUMERS SAFETY

Request for a scientific opinion on the Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products.

1. Background

The International Cooperation on Cosmetics Regulation (ICCR) is an international group of regulatory authorities for cosmetics from Brazil, Canada, the European Union, Japan, and the United States. This multilateral framework seeks to promote regulatory convergence, while maintaining the highest level of global consumer protection and minimizing barriers to international trade.

ICCR has identified the responsible handling of traces of banned substances as a topic of international relevance. As a result, it decided to work on this with a view of aligning on best practice among the ICCR regions, while fully respecting their specific regulatory regimes. To this end, a working group was created, which included experts from the jurisdictions' regulators and industry.

The group prepared a general Report for ICCR on Principles for Handling Traces in Cosmetics¹, which was published in 2011. In addition, among the substances of concern, it selected 1,4-dioxane which was assessed individually in order to identify harmonized best practices across the ICCR regions and give recommendations.

It should be made clear that these documents have no regulatory status. However, the report on 1,4-dioxane could be used as a supporting reference by market surveillance authorities in the EU and beyond, and as a useful starting point for discussion, should any of the ICCR regulators consider it useful to open a regulatory review.

We asked the SCCS to informally review the report on 1,4-dioxane, in order to flag any issues it might detect with the two documents or with the general approach used by the ICCR ad-hoc working group. We received an answer on 7 July 2013 (Ares(2013)2570845), which we shared with ICCR partners and used to review the reports.

While the Traces Working Group recommended a two-step approach with a starting acceptable and safe trace level of 1,4-dioxane at 25 ppm, followed by the phasing-in of a 10 ppm level over a short period of time, the SCCS did not support this approach. The SCCS considered that *"trace levels of 1,4-dioxane in cosmetic products representing a LCR < 10⁻⁵ is considered safe for the consumer. Thus, a trace level of 1,4-dioxane in cosmetic products of < 10 ppm is safe.*

¹ http://iccrnet.org/files/5714/0475/3672/2011-04_ICCR_Principles_for_Handling_Traces_in_Cosmetics.pdf

SCCS is of the opinion that a target level of less than or equal to 10 ppm of 1,4-dioxane in finished cosmetic products should be phased in over a short transition period."

In order to report the SCCS' position, we have to refer to the formal SCCS assessment in the report and to quote its findings.

2. Terms of reference

Could the SCCS give its scientific opinion on the "Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products"?

3. Planned Deadline: March 2016

4. Supporting documents

Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products.