

**1st Trier NGRA workshop 2025 at the Trier University, Germany****Endocrine disruption safety assessment approaches for cosmetics in the EU and beyond: role of Next Generation Risk Assessment**

Disruption of endocrine system homeostasis is a toxicological hazard, one which is under increasing regulatory scrutiny. Within the context of the EU Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the US Endocrine Disruptor Screening Project (EDSP), substances are systematically evaluated for endocrine disruption (ED) against three criteria: an endocrine mode of action, adverse effects in intact organisms or (sub)populations, and a biologically plausible link between the mode of action and the observed effect. For cosmetic ingredients, *in vivo* data generated after the EU 2013 ban of animal testing cannot be used to assess their safety, yet *in vivo* generated prior to the ban do not fully address current ED regulatory requirements.

In this context, the incorporation of results generated with new alternative methods into an integrated safety assessment has become imperative for cosmetics. Next Generation Risk Assessments (NGRAs) are a means to integrate historical *in vivo* findings and novel *in silico* and *in vitro* data into a single, transparent risk profile. The resulting Weight-of Evidence (WoE) evaluation provides a comprehensive assurance of human safety, leveraging data from the new alternative methods to plug current data gaps without the use of animal studies; in effect modernizing older data beyond their historical limitations. This is particularly critical for thyroid disruption, which under previous guidelines was only detectable as altered thyroid gland histopathology.

This workshop aims to address the scientific suitability of the approach for the safety assessment of cosmetic ingredients with potential endocrine activities; also considering the regulatory contexts of REACH, the EU Cosmetics Directive, the US Modernization of Cosmetics Regulation Act and the US Toxic Substances Control Act. Several practical state-of-the-art NGRA cases involving potentially endocrine disrupting substances and their WoE for human safety decision making will be discussed.

On behalf of the organizing team,



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