ISSUE 1

COSMETICS EUROPE RESEARCH NEWSLETTER

Cosmetics Europe
the personal care association

ADVANCING RESEARCH INTO ALTERNATIVES FOR SKIN SENSITISATION AND TESTING STRATEGIES

DEVELOPMENT OF ALTERNATIVE APPROACHES TO ANIMAL TESTING UNDER THE LONG RANGE SCIENCE STRATEGY (LRSS) PROGRAMME (2016-2020)

John Chave
Director-General, Cosmetics Europe

It gives me great pleasure to welcome you to this year's first edition of the Cosmetics Europe Research newsletter. This edition focuses on research into alternatives for skin sensitisation and testing strategies.

For more than 20 years, our industry's best scientists have been at the forefront of research into alternatives to animal testing (AAT) methods and approaches.

On this journey, our industry has taken a collaborative approach. For example, the SEURAT-1 (www.seurat-1.eu) research initiative was the largest private-public partnership in the field of AAT, and brought together over 70 partners. It was jointly funded by the European Commission and Cosmetics Europe for a total of €50 million. Continuing on the path of collaboration, Cosmetics Europe is also partner in the Horizon 2020 EU-ToxRisk (www.eu-toxrisk.eu) project where the goal is to achieve a paradigm shift in toxicology towards a more efficient and animal-free chemical safety assessment.

Building on our experience with SEURAT-1, we launched at the beginning of this year our multi-stakeholder Long Range Science Strategy (LRSS) programme. The objectives of the LRSS programme are multi-faceted and ambitious but in short, we want to be at the absolute forefront of financing, steering and promoting methods and approaches for AAT safety assessment and to facilitate their regulatory acceptance.

We have developed a dedicated roadmap for LRSS running until 2020 that outlines all annual milestones within each work stream, which include toxicokinetics, toxicodynamics, eye irritation, genotoxicity and skin tolerance. The majority of the resources in the LRSS research will be dedicated to toxicokinetics, toxicodynamics and skin tolerance.

In this edition of the newsletter, we will specifically look at: the latest developments of the Cosmetics Europe skin sensitisation programme and the IDEA Project, an open platform set up by our friends at the International Fragrance Association (IFRA).

I do hope you find it informative, and as ever, I would appreciate questions and comments that could help us shape future content according to your interests.

ADVANCING RESEARCH INTO ALTERNATIVES FOR SKIN SENSITISATION AND TESTING STRATEGIES

Dirk Petersohn
Chair, Cosmetics Europe Skin Tolerance Task Force

The Cosmetics Europe Skin Tolerance Task Force (TF) is working to strengthen our understanding of how chemicals react with the skin and activate the body's immune system to cause allergic contact dermatitis (ACD). This toxicological issue which affects approximately 15-20% of the human population represents one of the core components of the LRSS programme. 2016 sees us entering an exciting new phase of the project in this field with a number of key milestones.

Skin allergy affects approximately 15-20% of the human population

The goal of our task force is quite simple and straightforward: to provide regulatory accepted animal-free testing strategies that enable cosmetic industries to conduct skin sensitisation safety assessment. However, reaching this ambitious goal is demanding due to the complex biology behind induction of allergic contact dermatitis.

The first phase of the research programme started with the extensive screening and evaluation of 16 different *in vitro* test methods which had been developed to predict the sensitising characteristics of chemicals. Subsequently, the 6 most advanced methods prioritized in phase 1 were moved to phase 2, which focused on gathering experimental data about approximately 130 chemicals, covering the full range of skin sensitisation potency. Part of this work has been done in collaboration with the Research Institute for Fragrance Materials. All test results were then collated in a unique reference database for skin sensitisation, together with currently available human and historical local lymph node assay data (LLNA) on those chemicals. This comprehensive database enables us to analyse the skin sensitising properties of chemicals, the underlying physiological mechanisms and the productivity of the different test methods in an unprecedented way. It also allows us to evaluate the accuracy of available testing strategies.

In parallel, we have commenced phase 3 where we will further expand our database. Cosmetics Europe member companies have compiled a set of 50 chemicals with challenging physical-chemical properties that are of utmost importance for their business (e.g. hair dyes, UV-filters, mixtures, plant extracts or preservatives). On the basis of all results collected the TF will define the applicability domains of the six previously identified test methods and, in a next step, respective test strategies. Phase 4 will see the Task Force make use of what it has learned by conducting case studies, which is foreseen for 2017.

Clearly, conducting safety assessment of chemicals without the use of animals is not an overnight process, as the complex biology of skin sensitisation demands a sophisticated, tiered testing strategy. However, progress is thriving so far. The evaluation of a number of already defined and available testing strategies revealed a predictive accuracy comparable to the traditional LLNA, and we are looking to deliver more details with upcoming publications in peer reviewed journals. Current findings are presented during Cosmetics Europe Week, in Brussels.

INTERNATIONAL DIALOGUE FOR THE EVALUATION OF ALLERGENS: DRIVING PROGRESS THROUGH COLLABORATION

Matthias Vey
Scientific Director, IFRA

Although our industry has been developing alternatives to animal testing within the area of fragrance allergens for two decades now, most refined risk assessment methodologies have remained reliant on animal and human data. With Europe leading the way, the world has been moving inexorably towards a testing reality in which we solely utilise alternative and non-animal data. This represents a paradigm shift that requires the very best scientists from across our stakeholder universe to work together.

This forms the foundation of the International Dialogue for Evaluation of Allergens (IDEA) project, developed by the International Fragrance Association (IFRA) in collaboration with the European Commission.

"Dialogue through IDEA helps to build understanding and foster trust, contributing immensely to advancing consumer safety and well-being", explained Mr Vey. "It has become evident that the IDEA project model may have applications beyond fragrance skin allergies linked to the use of cosmetic products. This could support safety assessments performed across sectors, and thus bridging the most recent advancement in science to provide safe consumer products.

On the topic of alternatives, we are currently in the analysis phase, in which we seek to understand where we stand collectively, based on all available intelligence, and to hopefully identify valuable initiatives that may have been overlooked. At the most recent workshop, we learned that with the collective body of work available, we are getting closer to understanding potency and remain on track with hazard characterisation.

Based on the analysis, we will be able to identify gaps worthy of further research". A full report on the analysis phase will be made available over the course of the summer. More information is available at www.ideaproject.info.

The newsletter is published twice a year by Cosmetics Europe to bring you the latest news regarding the development of Alternative Approaches to Animal Testing. Each edition will focus on a particular topic of interest to the Long Range Science Strategy (LRSS) programme (2016-2020).

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