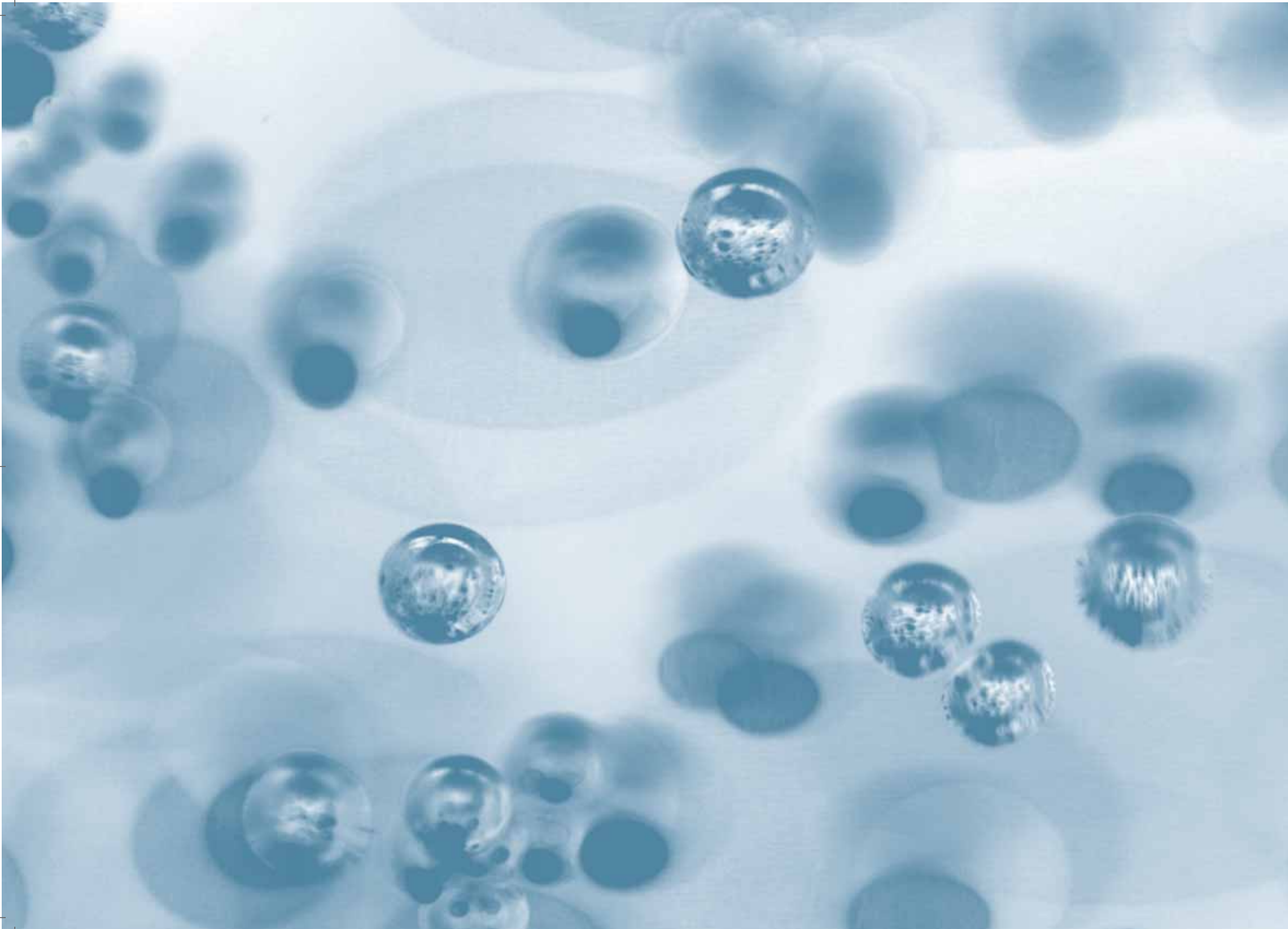


Colipa

Serious about *Cosmetics* - Serious about *Alternative Methods*



A shared commitment to consumer *safety*

The cosmetic industry sees consumer safety as its number one priority and therefore supports the strict EU regulations that are in place to ensure that consumers are safe and feel safe when using a cosmetic product.

The components of every cosmetic product on the market today have been evaluated to ensure that they do not cause any harm to the consumer. This is as true for cosmetic products as it is for food, clothing, medicines and most other products used by consumers. In the majority of cases, animal testing has been used in the safety evaluation of chemical components in consumer products.

Through the collaborative work we are doing together with our partners in Europe, we are at the forefront worldwide and call on regulators to seek a global solution: internationally agreed standards for non-animal chemicals testing, which are acceptable and applicable throughout the world.

An industry aiming for the elimination of *animal testing*

The cosmetic and personal care industry is committed to the eventual elimination of animal testing on the components of any consumer product and is proud of the important role it is playing in supporting this global cause.

We have assigned our best scientists, laboratories and significant funding towards this effort for more than twenty years.

However, gaps remain in the areas of greatest challenge for safety assessment such as repeat-dose systemic toxicity.

Animal testing: a reality across industry sectors to ensure consumer safety

Non-animal alternative methods are performed to test ingredients used in cosmetic products wherever possible and where appropriate. However, there remain several tests that are necessary to ensure that ingredients do not cause any harm to the consumer, for which non-animal alternative methods are not yet known or scientifically validated.

Scientific knowledge will need to be generated and new avenues explored to enable, for example, simulation of the systemic fate and effects of untested ingredients in the body.

Currently, animal testing takes place for these cases – but under the most stringent conditions and ethical policies. Such procedures rate among the most highly regulated and monitored in scientific laboratories today.

Whilst many cosmetic and personal care products could be labelled ‘not tested on animals’, Colipa members feel that this could be misleading. Although finished products are no longer tested in this way, the safety information for all ingredients used in existing product formulations has been developed from previous safety packages which include animal studies.

The safety of our products is, and must always remain, the number one priority. Any new alternative approaches for safety assessment must be validated and be shown to provide at least an equivalent level of consumer protection to that provided based on current methods.

Working hard together for a world without animal testing

The development of alternative methods necessary to ensure consumer safety requires scientific knowledge which is the result of detailed and time-consuming scientific research. It is therefore very difficult to be precise about the timeframe for the introduction of further alternative methods.

The progress made in biological research cannot be predicted and its success is not directly proportional to the amount of money and effort invested in the cause. For example, some of the world’s most high profile diseases remain incurable – this, in spite of the billions of Euros spent on a search that has been pursued over time by some of the scientific world’s brightest minds.

Currently, non-animal replacements to obtain some of the most complex toxicological knowledge necessary to ensure the safety of new ingredients represent a considerable scientific and technical challenge for the future.

To respond in a positive way to the challenges of developing alternative approaches to animal testing for safety assessments, the cosmetic industry is taking a lead-role in certain areas of research and must work in partnership with other stakeholders for the remaining areas, as we cannot cover alone the whole field of toxicology.

What is an alternative method?

Scientists define an alternative method as one of the **Three Rs**. – either a **Replacement** of an animal test by a non-animal test; a **Refinement** of an animal test to reduce stress or suffering; or a **Reduction** in the number of animals used in a test.

Alternative testing methods are scientifically validated by the European Centre for the Validation of Alternative Methods (ECVAM). This means that they must be applicable across the different industries that test for safety purposes (chemicals, food, pharmaceuticals, etc).

Validation is the process by which scientists and regulators establish whether a method is reliable and relevant for a specific purpose. As an example, *in-vitro* skin models are validated to replace the skin corrosion test which does not take place on animals any more. This particular alternative method evaluates irreversible destruction of tissue by a chemical but not, for instance, milder irritant effects.

A long-term commitment that has already delivered

Member companies have spent years gathering experience in their particular product areas and producing concrete results. Using state-of-the-art science, advanced approaches to risk assessment and the extensive results already in existence, the cosmetic and personal care industry pooled its resources and succeeded in replacing all animal testing of finished products by *in-vitro* testing in the late 1980s. For ingredients, this very difficult process has now been well underway for some years.

The cosmetic industry conducts numerous research initiatives. In 1992, Colipa created the Steering Committee on Alternatives to Animal Testing (SCAAT) to coordinate the efforts of the cosmetic industry in the development and acceptance of alternatives to animals in safety evaluation.

The work of SCAAT is based on collaboration – not only between member companies – but also with other groups who have a legitimate interest in the outcome of the research.

SCAAT partners with academia, other industrial trade associations, the German Centre for the documentation and evaluation of Alternatives to Animal Testing (ZEBET), the European Commission’s Scientific Committee on Consumer Products (SCCP), ECVAM, and the European Commission’s DG Enterprise, DG Research and Joint Research Centre (JRC).



Results that are making a difference

Four replacement methods to animal testing based on strong contributions from the cosmetics industry have been developed. Of these, three have to date been validated by ECVAM. The fourth, an *in-vitro* method for dermal absorption/percutaneous penetration, has been officially accepted by the Organisation for Economic Co-operation and Development (OECD).

Topic	Explanation		Replacement
Skin corrosion	Irreversible destruction of tissue by a chemical	1	Transcutaneous Electrical Resistance Assay
		2	Human skin models
Phototoxicity	Toxicity that occurs when a substance is exposed to ultraviolet (UV) light	3	3T3 Neutral Red Uptake Phototoxicity Test
Percutaneous absorption	Absorption of a substance through the skin	4	<i>In-vitro</i> method

The industry is proud of the scientific achievement in the validation of these tests and the important role that it is playing in contributing to the global reduction in the amount of tests carried out on animals.

In addition to these approved **R**eplacement methods, the industry has developed many **R**efinement and **R**eduction alternatives which are used in-house by companies. All have contributed significantly to reducing the number of tests on animals and the industry continues to share this global goal.

PHOTOTOXICITY a success story... after 8 years

- 1991** The cosmetic industry meets with EU regulators to review protocols for a new non-animal test.
- 1992** First collaborative study is conducted with ZEBET and ECVAM. Successful outcome is obtained for the 3T3 Neutral Red Uptake Test.
- 1995** Two tests are proposed for formal validation.
- 1997** The study is successful and the 3T3 NRUPT is validated.
- 1999** A third study is conducted and regulatory approval is obtained. Tests on animals are replaced by *in-vitro* tests.





The Skin Tolerance Task Force

The Skin Tolerance Task Force is working to strengthen our appreciation of how chemicals bind to proteins and so cause skin allergies. The goal is for an *in-vitro* protein binding assay that will serve as an allergy screen. One potential *in-vitro* assay has already been developed to make this measurement and a second approach is under active consideration.

Dendritic cells are the key cells responsible for taking an allergen to the immune system - the event leading to allergy induction. The Skin Tolerance Task Force aims to harness existing knowledge of dendritic cell biology for the development of surrogate *in-vitro* assays.



To enhance our incomplete understanding of dendritic cell biology, the Skin Tolerance Task Force is analysing changes in gene expression associated with allergen exposure. This work has led to proposals for assay development that are now under active review. Colipa funded research on these key cells is also underway in another scientific field - trying to understand how the dendritic cell recognises and signals the danger that allergens present.

The Skin Tolerance Task Force has run a series of projects on skin irritation, aimed at enhancing our understanding of how irritants change both gene expression and cause modulation of the release of cell signalling proteins (cytokines). Two extensive studies have recently been completed and the results are being analysed to determine what opportunities there may be for *in-vitro* assay development.

The Genotoxicity Task Force

The **Genotoxicity Task Force** is working together with external partners like academia and ECVAM in order to develop new *in-vitro* assays which are capable of increasing the specificity of the actual standard *in-vitro* tools in genetic toxicology.

Current *in-vitro* tests allow the sensitive detection of possible carcinogens, however they are known to lead to a high percentage of false positive results and therefore their specificity is very low. The Genotoxicity Task Force is currently analysing the key causes for the differences observed between *in-vitro* and *in-vivo* genotoxicity testing and is developing projects which are aiming to clarify positive findings from the standard *in-vitro* assays on the basis of *in-vitro* experiments.

For cosmetics the most relevant route of exposure is the dermal route. The first focus of Genotoxicity Task Force will therefore be on genotoxicity assessment using models like 3D human skin equivalents like skin metabolism and skin penetration that are not covered in the standard assays.

The goal for the development and validation of these methods is to lead to replacement of animal experiments and, at the same time, to generate results with higher significance for the dermal route of exposure.

The Eye Irritation Task Force

The **Eye Irritation Task Force** incorporates integrated research projects and collaborative activities with external partners focusing on understanding mechanisms of eye injury and identification of new *in-vitro* endpoints that are more predictive of the *in-vivo* human response to chemical injury. There are three projects:

- 1) Investigation of whether kinetics/patterns of change in physiological function and signals of injury released from the cornea *in vitro* can predict a chemical's potential to damage the eye with a focus on recovery.
- 2) Identification of endpoints related to magnitude of injury and quality of repair in human immortalised cells and 3-dimensional human corneal and conjunctival constructs.
- 3) A genomics project using a pattern recognition approach to identify new endpoints for injury and repair that build on corneal models being evaluated in projects 1 and 2 for potential use in current/future *in-vitro* assays.

Equally important to achieve validated *in-vitro* methods is collaboration of industry, academia, external scientific organisations and regulators. Colipa is working with ECVAM by actively participating in its Eye Irritation Task Force and providing support for post-hoc statistical analysis of current *in-vitro* methods.

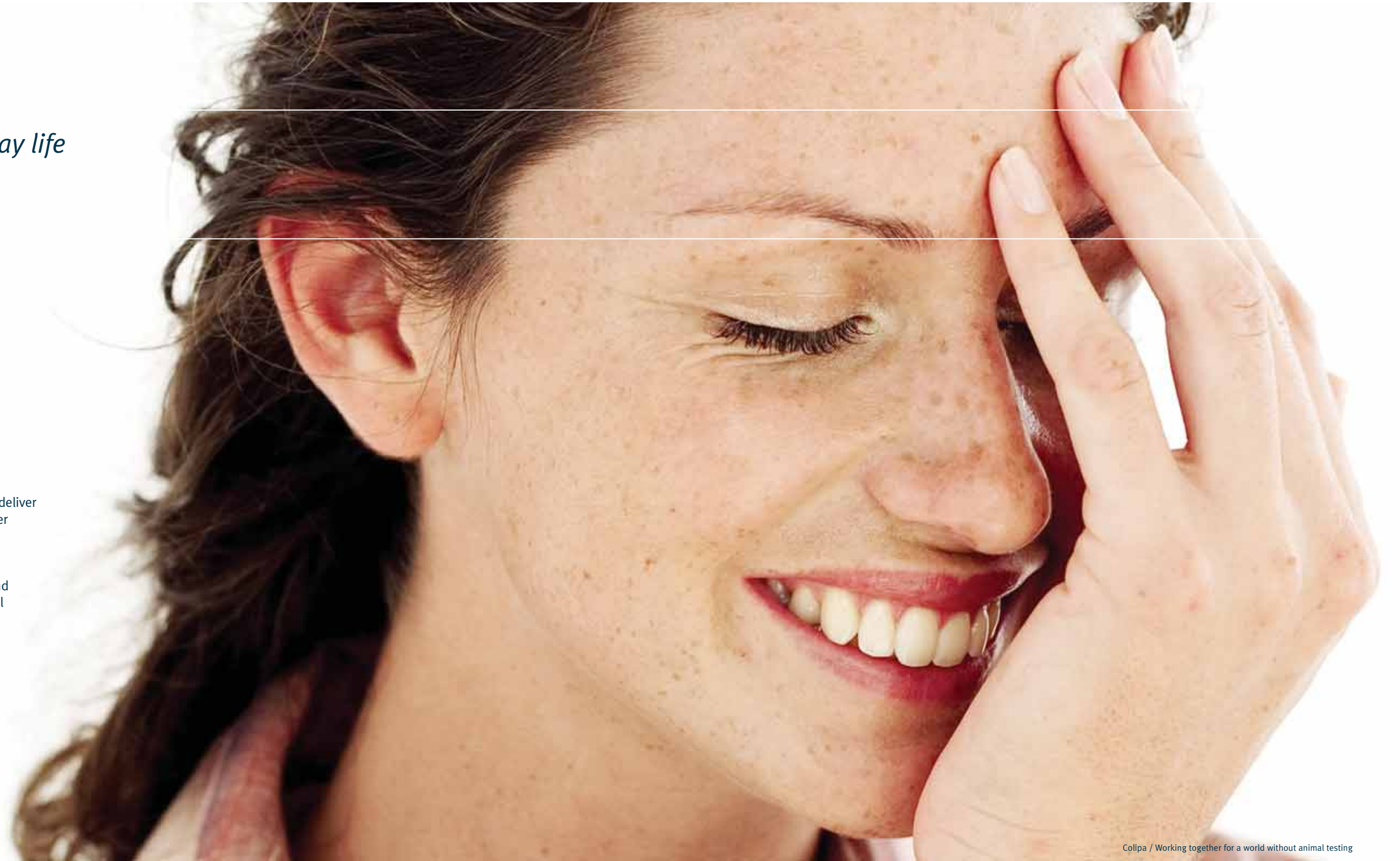
Cosmetics: *a fundamental part of everyday life*

Cosmetics are part of the universal pursuit for well-being and beauty, helping millions of consumers to feel good about themselves and full of confidence every day. Cosmetics have played a fundamental role in the evolution of personal hygiene and skin protection. The use of cosmetics is also an act of self-expression that is independent of age, cultural background or gender.

The average European will use at least six cosmetic and personal care products every day. In other parts of the world, such as Korea, this number can reach 22.

The cosmetic industry strives to satisfy consumers' expectations for products that deliver the best and newest in performance, safety and environmental awareness. In order to fulfil these expectations, the industry invests heavily in research development, using cutting edge technology and state-of-the-art science.

Innovation is driven by the desire for continual improvement, not only in safety and efficacy, but also to ensure progress on sustainability. This important progress will undoubtedly result in the discovery of new ingredients that will need to be shown as safe for human use.



Colipa: *serious* about cosmetics - *serious* about alternative methods

For more than 40 years, Colipa has represented the European cosmetic, toiletry and perfumery manufacturing industry in Brussels.

Working together with the European Institutions, NGOs and other industry sectors, Colipa is committed to contributing to the regulatory framework for cosmetics in the best interests of consumers, innovation and competitiveness.

Encouraging best practice through shared industry expertise, Colipa is the voice of an innovative and responsible world-leading industry that injects 60 billion Euros per annum into the European economy, employs 150 000 Europeans directly and further supports the employment of 350 000 working in retail, distribution and transport sectors.

From family owned SMEs to multi-nationals, Colipa's membership includes more than 2000 companies and 23 national associations, all of whom contribute to its work.



COLIPA IS THE EUROPEAN TRADE ASSOCIATION REPRESENTING THE INTEREST OF THE COSMETIC, TOILETRY AND PERFUMERY INDUSTRY.

MEMBER ASSOCIATIONS

AUSTRIA

F.C.I.O. - Fachverband der Chemischen Industrie Österreichs

BELGIUM & LUXEMBOURG

DETIC – Association Belgo-Luxembourgeoise des producteurs et des distributeurs de savons, cosmétiques, produits d'entretien, d'hygiène et de toilette, colles et produits connexes

CZECH REPUBLIC

CSZV - Czech Association for Branded Products

DENMARK

S.P.T. – Brancheforeningen for Sæbe, Parfume og Teknisk/Kemiske artikler

ESTONIA

EKTL (FECI) – Eesti Kutseliste Tantsijate Liit

FINLAND

T.Y. - Teknokemian Yhdistys Teknokemiska Föreningen

FRANCE

F.I.P. - Fédération des Industries de la Parfumerie

GERMANY

I.K.W. - Industrieverband Körperpflege- und Waschmittel

GREAT BRITAIN

C.T.P.A. - Cosmetic, Toiletry & Perfumery Association

GREECE

P.S.V.A.K. - The Hellenic Cosmetic, Toiletry and Perfumery Association

HUNGARY

KOZMOS - Hungarian Cosmetic and Home Care Association

IRELAND

I.C.D.A. - Irish Cosmetic, Detergents & Allied Products Association

ITALY

UNIPRO - Unione Nazionale delle Industrie di Profumeria, Cosmesi, Saponi da Toilettia e Affini

LATVIA

Association of Latvian Chemical and Pharmaceutical Industry

LITHUANIA

LIKOHEMA - Lithuanian Cosmetics and Household Chemicals Producers Association

THE NETHERLANDS

N.C.V. - Nederlandse Cosmetica Vereniging

NORWAY

K.L.F. - Kosmetikkleverandorenes Forening

PORTUGAL

A.I.C. - Associação dos Industriais de Cosmética, Perfumaria e Higiene Corporal

SLOVAKIA

Slovak Association for Branded Products

SLOVENIA

KPC - Association of Cosmetics and Detergents Producers of Slovenia (part of the Association of Chemical Industries)

SPAIN

STANPA - Asociación Nacional de Perfumeria y Cosmética

SWEDEN

K.T.F. - Kemisk-Tekniska Leverantörförbundet

SWITZERLAND

SKW. - Schweizerischer Kosmetik-und Waschmittelverband

MEMBER COMPANIES

Avon

Beiersdorf

Bourjois

Chanel

Christian Dior

Colgate Palmolive

Coty

Elizabeth Arden

Estée Lauder

Laboratoires Expanscience

GlaxoSmithKline

Henkel

Johnson & Johnson

Kanebo Cosmetics

Kao Corporation

L'Oréal

Mary Kay

Pierre Fabre

Procter & Gamble

Shiseido

Unilever

Wella

YvesSaintLaurent

COLIPA - THE EUROPEAN COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION

Our Vision

The cosmetics, perfumery and personal care industry and its products significantly contribute to individual and social well being in our everyday lives.

Our Mission

To help maintain and develop a sustainable, competitive and respected industry in Europe

- by demonstrating the inherent value of our industry (as stated in our vision)
- by striving to create the most favourable economic and regulatory environment in which to operate
- and by advocating best practices, thereby ensuring that consumers benefit from continuously innovative and safe products.

Our Goals

Colipa, as THE recognised voice of the European cosmetics, perfumery and personal care industry, must:

Earn public trust

by fostering transparent and reliable relationships with public authorities and stakeholders, to best communicate the social and economic relevance of our industry in terms of satisfying consumer needs.

Achieve effective public policy

by actively contributing to the shaping of workable and fair policy frameworks regulating the industry. To this end, proactive and effective networking and communication are of the essence. Opportunities for achieving alignment on an international scale should be created and optimised.

Enhance member value

by addressing members' needs in an efficient and transparent way, through timely information and decision making processes and focusing on the issues and activities which are important to them.

Best use should be made of members' expertise and dedication to optimise both efficiency and one-voice positions.



COLIPA - The European Cosmetic, Toiletry and Perfumery Association

Avenue Herrmann-Debroux 15A - B-1160 Brussels

Colipa Contact Information: Sebastian Marx

T: +32 2 227 66 19

F: +32 2 227 66 27

E: smarx@colipa.be

www.colipa.com

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ASSOCIATION REPRESENTING THE INTEREST OF THE
COSMETICS, TOILETRY AND PERFUMERY INDUSTRY

COSMETICS EUROPE – THE PERSONAL CARE ASSOCIATION
AVENUE HERRMANN-DEBROUX 40, 1160 BRUSSELS
T. +32 2 227 66 10, F. +32 2 227 66 27
WWW.COSMETICSEUROPE.EU