Colipa
Serious about Cosmetics - Serious about Alternative Methods
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 chemical testing, which are acceptable and applicable throughout the world.

A shared commitment to consumer safety

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 the 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.

An industry aiming for the elimination of animal testing
Animal testing: a reality across industry sectors to ensure consumer safety

Non-animal alternative methods are performed to test ingredients used in cosmetic products whenever 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 proven or scientifically validated.

Scientific knowledge will need to be gained and new avenues explored to enable, for example, variances of the systemic toxic and effects of unknown ingredients. Today, 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 testing.

Currently, animal testing takes place for these cases – but under the most stringent conditions and ethical policies. Such procedures rank 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 testing.

The development of alternative methods necessary to ensure consumer safety requires scientific knowledge which is the result of detailed and intensive carrying out of 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 it. 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.

Validations are 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 test, for instance, inden in a test.

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 effort of the cosmetic industry in the development and acceptance of alternatives to animal 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 academic, other industrial trade associations, the German Centre for the documentation and evaluation of Alternatives to Animal Testing, 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).

Member companies have spent years gathering experience in their particular product areas and producing concrete results. Using epidermal-in vitro 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 for the validation of finished products by in-vitro testing in the last 20 years. For ingredients, this very difficult process has now been underway for some years.

The cosmetic industry conducts numerous research initiatives. In 1995, 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 animal safety evaluation.

Colipa / Working together for a world without animal testing

Working hard together for a world without animal testing

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 Reduction of an animal test to reduce stress or suffering, or a Validation of the number of animals used in a test.

Replacement 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 test, for instance, inden in a test.

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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).

In addition to these approved replacement methods, the industry has developed many refinement and reduction 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.

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

**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 Phototoxicity 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 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 measure this measurement and a second approach in 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 recognizes and signals the danger that allergens present.

The Skin Tolerance Task Force has run a series of projects on skin irritation, aimed at understanding the molecular and biological processes that cause modulation of the release of cell-signalling proteins (cytokines). Two extensive studies have recently been completed and the results are being reviewed to determine what opportunities there may be for in-vitro assay development.
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 the Eye Irritation Task Force and providing support for post-hoc statistical analysis of current in-vitro methods.

The Genotoxicity Task Force is working in close cooperation with external partners like academia and industry in order to develop new guidelines which aim at improving 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 high percentages of false positive results and therefore their predictivity is very low. The Genotoxicity Task Force is currently analyzing the key causes for the differences between in-vitro and in-vivo genotoxicity testing. The focus is on the development of new in-vitro methods which are able to clearly position findings from the standard in-vivo assay as the basis of in-vitro equivalents.

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 to mimic inflammation and skin penetration that are not covered in 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 Genotoxicity Task Force
Cosmetics are a 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 fulfill 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.

Cosmetics: a fundamental part of everyday life
Colipa: serious about cosmetics - serious about alternative methods

For more than 40 years, Colipa has represented the European cosmetic, toiletry and perfume 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 / Working together for a world without animal testing
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 recognized 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.

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