40 Years of EU Cosmetics Legislation
1976 - 2016

Celebrating 40 years of EU cosmetics legislation

1976 – Establishment of the Scientific Committee on Cosmetology (SCC – now abbreviated SCCS)

The EU created a panel of independent experts, chosen for their scientific excellence and independence, to advise on safety of cosmetic ingredients in a transparent manner and on science-based reasoning.

Renewed several times over the years, this committee is internationally recognized and its opinions serve as the basis for regulatory decisions beyond the EU.

1979 – Adoption of the Cosmetics Directive 76/768/EEC

The Member States of the European Economic Community (now called the European Union - EU) decided to harmonize their national cosmetic regulations in order to ensure **a high level of consumer protection and enable the free circulation of cosmetic products within the Community**.

1980's – Positive List of Preservatives

The EU – with the support of its scientific committee SCCS - **set up a list of substances that can be used as preservatives in cosmetics and the conditions / concentrations that need to be respected.**

Cosmetic companies can only use those substances as preservatives. Any new preservative must first be evaluated, found safe by the SCCS and added to the list before it can be used.

1990's – Positive List of UV Filters

The EU - with the support of its scientific committee SCCS – **set up a list of substances that can be used as UV filters in cosmetics**. Whilst the data requirements for new UV filters are high, they are clearly described by the SCCS guidelines and industry can operate in a predictable and transparent approval environment. This has allowed the EU industry to become the global leader in UV filters sun protection.

1993 – 6th Amendment to the Cosmetics Directive 76/768/EEC

This Amendment refined and completed the main principles of the EU Cosmetics Regulation which have since become the model and inspiration for many emerging regions of the world:

- **Risk-based regulation** aiming at a high level of consumer protection
- **Mandatory safety assessment** of every product placed on the market, to be carried out by a suitable and trained safety assessor
- Every product must have a **comprehensive technical information file** that is accessible to control authorities during in-market control
- Industry responsibility represented by the '**Responsible Person**'
- Member States authority obligation to carry out **effective in-market control**
- Full ingredient labeling using **INCI nomenclature**

Consumers can, with help of the INCI (International Nomenclature of Cosmetic Ingredients) name, recognise ingredients on the label when buying a cosmetic product anywhere in the EU.

1997 – Addressing New Challenges for Risk Assessment and Risk Management

In the wake of the BSE food crisis, the EU Commission decided to clearly separate the functions of **risk assessment** (SCCS) and **risk managemen**t (legislation) to ensure their independence. Since then, the two responsibilities are managed by different Departments / Directorate Generals in the EU Commission.

2000 – First Alternative Method Validated / Accepted for Cosmetics

The term "alternatives" was coined by the distinguished physiologist David Smyth in his 1978 book *Alternatives to Animal Experiments*. It is used to describe any change to established scientific procedures that will result in the replacement of animals. **Alternative Skin irritation tests became available in 2000 after they had been validated by ECVAM and adopted by the EU and OECD.**

Already during the 1960s the biologist Bruce Ames developed an alternative method i.e. an in vitro test in bacteria that still carries his name and that is still used as a relatively inexpensive way to assess the mutagenic potential of many substances including cosmetic ingredients.

2001 – A New Approach to Chemicals Legislation in the EU with REACH

Chemicals placed on the EU market – be it as such or as part of a finished product, need to be registered with **a safety data package and a human and environmental safety assessment**. Cosmetic ingredients are covered by this registration obligation.

REACH is the most important piece of environmental legislation for the substances used in cosmetics.

2003 – 7th Amendment to the Cosmetics Directive

Besides refined consumer information requirements on the presence of certain allergens and on product durability, this amendment brought two major changes:

- **The animal testing bans for cosmetic ingredients**, which up to this time were dependent on the availability of alternative methods, were linked to fixed deadlines (2009 and 2013) – irrespective of the scientific progress and availability of alternative methods
- **A categorical, hazard based ban** in cosmetics of the use of substances classified under the Chemicals legislation as CMR Cat 1A or 1B – irrespective of whether such use in cosmetics is safe or not

2004 – Enlargement/ TAIEX

During several rounds of EU Enlargement a total of 22 new Member States adopted the EU Cosmetics Directive since 1976 and implemented it into their national laws.

Each time, significant preparatory work was carried out between the accession countries, both at industry level and authorities' level, and the EU Commission and industry associations. So-called **TAIEX seminars** allowed the accession countries to get a good **understanding of the harmonised EU legislation**, including on cosmetics. This ensured a smooth transition and integration of these countries and their products into the EU internal market.

2009/13 – New EU Cosmetics Regulation Enters into Force

Followed by an adoption in 2009, the year of 2013 finally marks the 'apotheosis' of the harmonised cosmetics legislation in the EU. **Changing the legal form from a Directive to a Regulation** means that the EU legal text no longer needs to be transposed into the national legislation of the Member States (sometimes slow and imperfect), but the EU text is as such the directly applicable law in all EU Member States.

The new Regulation also introduced a single, electronic product notification system (CPNP) that replaced the more than 20 different national systems existing at that time.

2013 – Animal Testing Ban of Cosmetics Ingredients Came Fully into Effect

The testing ban was already in place since 2009 (but testing for certain complex endpoints could still be done outside the EU) – **since 2013 it also became prohibited to market products that contained ingredients which were tested on animals** (including for the toxicological endpoints that were exempted in 2009 – as from 2013 the ban is complete both for testing and marketing).