BUSINESS PLAN

CEN/TC 392
COSMETICS

EXECUTIVE SUMMARY

Business Environment

Production and trade:

- The total EU28 market volume in 2014 is estimated around 72 500 000 000 EURO;
- The export volume outside the EU28 market in 2014 is estimated around 16 400 000 000 EURO;

A study carried out by DG Enterprise & Industry estimated 4400 companies (mainly SMEs) operating in the cosmetic sector in 2014. The European Cosmetic Industry is a significant employer: over 1 700 000 people are employed directly (source: Cosmetics Europe, Euromonitor international, 2014).

The regulatory framework is provided by the Cosmetics Products Regulation, EU Regulation 1223/2009.
Parties involved in standardization of cosmetics are:

- the cosmetics industry (companies and trade associations)
- suppliers/raw material and packaging industry
- consumer organizations
- professional users
- national governments/legislators
- laboratories
- research institutes
- environmental agencies
- NGOs

CEN/TC 392 works in close cooperation with ISO/TC 217 'Cosmetics' for a number of standards that are developed under the Vienna Agreement, thus seeking to ensure common international requirements, both within and outside Europe. CEN/TC 392 works also in close cooperation with CEN/TC 347 ‘Methods for analysis of allergens', CEN/TC 55 'Dentistry', CEN/TC 352 ‘Nanotechnologies’, ISO/TC 106 'Dentistry' and ISO/TC 229 ‘Nanotechnologies’ on overlapping fields. When a CEN/TC on biobased products will be established CEN/TC 392 may ask for a technical cooperation with this TC.

Compliance with Community laws on safety and efficacy of cosmetic products is ensured by Member States via in-market controls. The Commission assists Member States in coordinating these activities through the ‘Platform of European Market Surveillance Authorities for Cosmetics’ (PEMSAC). Therefore CEN/TC 392 and PEMSAC keep close ties.

Benefits

The benefits are that users of the standards have the possibility to use methods which:

- correspond to the need, e.g.
    - Safety
    - Free circulation of cosmetics
    - Market control/legislation
- have been tested for applicability;

- have (when possible) already been agreed;
- are written in a clear manner;
- have high levels of recognition compared to non-standardized methods;
- accessible for all companies including SMEs;
- presume compliance if methods are linked to legislation;
- are harmonized and overlap of work was avoided due to close cooperation with other method developing bodies.

By applying the standards developed by CEN/TC 392, cosmetics industry and consumer product control will avoid generating conflicting results when using different methods.

Priorities

Make European standards available related to EU legislation/official control, quality assurance in industry and trade contracts. CEN/TC 392 sets priorities for methods to be standardized according to the current EU-legislation and actual needs.

Scope of CEN/TC 392

The purpose of the CEN/TC 392 is to develop appropriate standards in the field of cosmetics to the final benefit of consumer health and well being. However, it is recognized that certain products (substances or mixtures), although applied to the body for permanent decorative purposes, do not fall under the definition of cosmetic products. CEN/TC 392 will consider such products when appropriate and justified by shared technical challenges.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics give a short description of the business environment of the cosmetics industry sector and its products. Related to the scope of this CEN/TC, they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

The Cosmetics industry is a global industry within which the EU is a major player. The output of EU cosmetics companies is around twice that of Japanese and USA companies. About 1 700 000 people are employed directly by cosmetics companies or indirectly in retail, distribution and transport (Source Euromonitor). Although the EU market for cosmetics is significant, valued at around 72,5 billion EURO in 2014, exports constitute a significant proportion of the market for EU manufacturers.
The cosmetics sector is characterized by global brands, with most multinational companies selling a high proportion of their products across all key markets. However, among more than 4400 EU cosmetics company, the majority is SMEs.

In 2014, trade with countries outside of the EU28 reached 16 400 000 000 EURO.

Cosmetics products are subject to regulatory controls in all markets, in order to ensure the safety of products and avoid adverse impacts on the health of users. The regulatory framework is provided by the Cosmetic Products Regulation, EU Regulation 1223/2009. With the Cosmetics Regulation Europe is having a robust, internationally recognized regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials. Regulation is applicable since 11 July 2013. The ban and the strict regime aiming at phasing out animal testing were not modified.

EU Regulation 1223/2009 replaces the Cosmetics Directive 76/768. The key elements of the EU Regulation include:

- Manufacturers' or importers' responsibility for ensuring that their products are safe and meet the requirements of the Regulation.
- Within each Member State, Competent Authorities have been designated to implement and enforce the Regulation. Though the Regulation is not explicit about this role, authorities undertake
  periodic in-market surveillance of products to ensure that they meet the requirements of the Regulation.
- Manufacturers or importers are required to keep a Product Information File (PIF) for each of their cosmetics products, including details on product ingredients, safety assessments, proof of any claims made etc.
- The Regulation specifies labeling requirements, which must include listing of ingredients, usage precautions, the address of the manufacturer or importer, and the information on product
  durability.
- An annexed list of ingredients that are banned, restricted or permitted (through the positive lists) in cosmetics products. The decision whether to include – or remove – an ingredient in one of the annexes is made by the European Commission, advised by the independent Scientific Committee on Consumer Safety (SCCS).

The system of the EU Regulation is thus characterized by a full responsibility of the manufacturer/importer for regulatory compliance and product safety, coupled with an authorities' responsibility for carrying out in-market control.

This approach ensures a clear allocation of responsibilities and a high level of consumer protection without the need for pre-market authorization of products. The EU regulatory framework has enabled continued innovation and enhanced the competitiveness of the industry, compared to frameworks in other markets, whilst maintaining a reputation of EU cosmetic products as safe and performing.

In order to keep this regulatory system working smoothly, industry, trade and the authorities have an interest in good quality cosmetic products that are controlled in a reliable way. Scientifically valid and agreed methods are useful for a uniform judgment of conformity of products and processes to the requirements and specifications, in particular in the framework of Safety evaluation, Quality Assurance, integral control of the production chain and for authorities' in-market control:

- Internationally recognized methods (e.g. of OECD and of ECVAM) are widely used in the safety evaluation of cosmetics.
- International standardized methods (e.g. of ISO) are widely used or under development in areas related to production (Good Manufacturing Practices, microbiological quality management, analytical methods for nitrosamines) or sunscreen efficacy testing.
- Official analytical methods for in-market control purposes have been developed in the past for specific ingredients, but individual national methods persist.

In the European Union and the European Economic Area, European Standards can play an important part in harmonizing diverging national standards of the member states and in supplying the specific European needs of industry, international trade and control authorities.

European Standards can contribute to facilitating compliance and control in particular through:

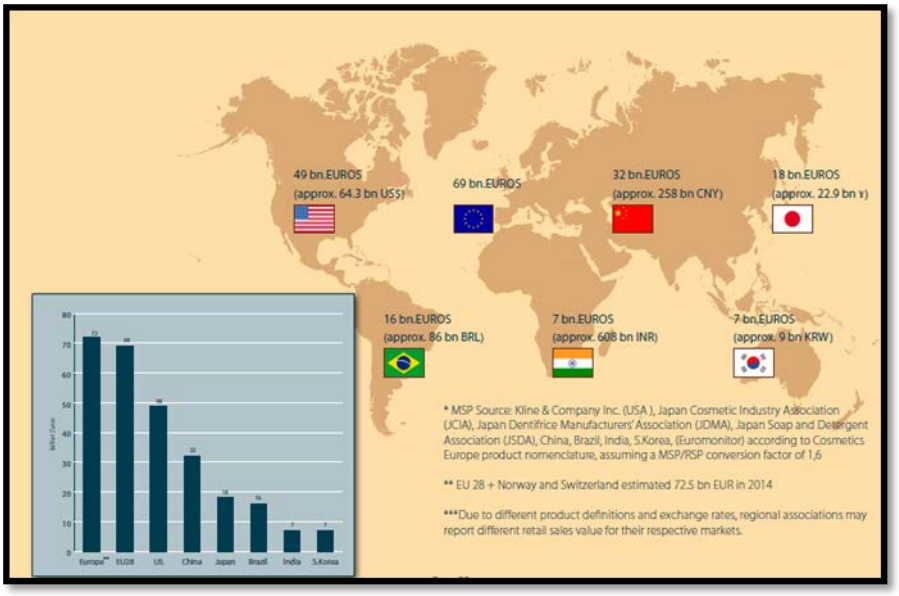
- Transposition of relevant ISO standards.
- Development of European Standards where required in relation to specific requirements of the EU Regulation.
- Development of European Standards when the ISO requirements over pass the current international need.

Development of European standards in identified areas relevant for in-market control, such as analytical methods/approaches, that can also be proposed to ISO.

1.2 Quantitative Indicators of the Business Environment

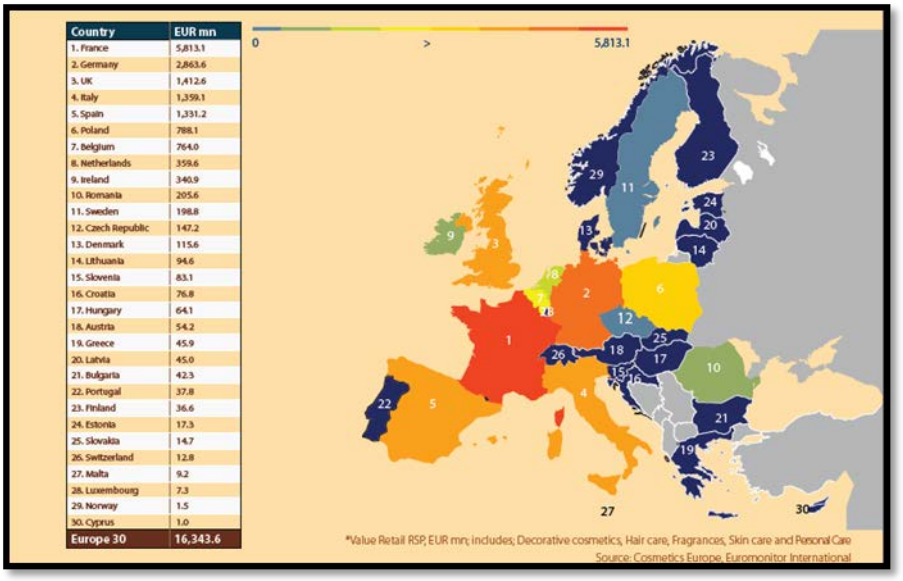
The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN /TC:

Fig. 1 - Overview of Global Cosmetics and Toiletries market: Value comparaison of European, USA and Japanese markets in 2014.



Source: Cosmetics Europe, Euromonitor international

Fig. 2 – European Cosmetics and Toiletries* Export (Extra EU28) in 2014: Eur 16 400 000 000. The European market represented almost one third of the global market



* *Value Retail RSP, EUR mn; includes; Decorative cosmetics, Hair care, Fragrances, Skin care and Personal Care

Source: Cosmetics Europe, Euromonitor International

The availability of European Standards means that official or private contract laboratories for quality and safety control or industry in all countries can use the comprehensive list of methods provided by national standardization institutes, of which each method gives repeatable and reproducible results. Time-consuming double research to find out which method could be the appropriate one for a given problem will become more and more superfluous. The money such laboratories save due to the availability of a list of methods (i.e., list of European Standards) cannot be calculated accurately, however, it can reasonably assumed to be enormous.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The availability of standardized methods is of utmost importance to fulfill the requirements of a free movement of goods in the common market. The basis for such and common assessment of cosmetics is set up by standardized methods.

Official or private inspection laboratories in all CEN-member countries can make use of the work of CEN/TC 392, i.e. of the comprehensible list of methods that give reliable and reproducible results according to article 12 of the EU Regulation 1223/2009. In those cases, where already horizontal standards have been elaborated, it is no longer necessary for technicians in the laboratory to carry out time consuming duplicate research, which method could be the most appropriate for a given problem.

The fact that all European inspection laboratories will be familiar with the same methods enables laboratories to exchange their experiences and to easily develop and improve the methods.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objective of CEN/TC 392 is to consider all topics, methods or proceedings related to cosmetics with as current priorities:

- Methods that are mandated by the EU/EEA
- Methods for traces
- Methods to identify and quantify ingredients
- Methods for testing cosmetic emulsion stability
- Methods to evaluate the efficacy of cosmetic products
- Microbiological standards and limits
- Methods for preservation of cosmetic products

It is noted that the feasibility of the above mentioned possible areas of work shall be considered following discussion in the CEN/TC 392.

Cosmetics are defined as in the Cosmetics Products Regulation, EU Regulation 1223/2009.

4.2 Identified strategies to achieve the CEN/TC.s defined objectives.

Points of interest of CEN/TC 392 in order to prioritize projects and produce European standards:

- Promote the expert work carried out by CEN/TC 392 and encourage the participating

organizations to provide experts.

- Secure the funding for CEN/TC 392 activities to be completed in a timescale which meets the requirements of European legislation and reduce the barriers to trade.
- Liaise and consult with stakeholders, involving appropriate experts, when necessary for new work items (tools), especially legislators and industry.
- Where applicable, undertake the field validation of proposed standards to ensure that repeatability and reproducibility levels can be established which provide confidence in the use of the methods and enhance European harmonization. Encourage the provision of funding for field validation work.
- Identify research needs.
- Review the work program every year.
- Take into consideration the information provided by the liaison members of CEN/TC 392 and other organizations and working groups in regular contact with CEN/TC 392, which are:
    - European Commission (in particular DG Enterprise and Industry and PEMSAC)
    - CEN (European Committee for Standardization) and in particular CEN/TC 55, CEN/TC 347, CEN/TC 352
    - Council of Europe in particular OCCL (Official Cosmetics Control Laboratories) at EDQM (European Directorate for the Quality of Medicines & HealthCare)
    - Cosmetics Europe
    - EFfCi (European Federation for Cosmetics Ingredients)
    - SBS (Small Business Standards)
    - TIME (Tattoo Ink Manufacturers of Europe)
    - ISO (International Organization for Standardization) and in particular ISO/TC 217 and ISO/TC 106 and ISO/TC 229
    - Stakeholder trade associations
- CEN/TC 392 will actively pursue the co-operation with ISO/TC 217 'Cosmetics' according to the Vienna Agreement.

CEN/TC 392 has at the moment the following organizational structure with WGs (Working Groups) and no more CAGs (Chair Advisory Groups). The proposal to convert CAG 1 ‘Skin compatibility’ into a new working group (WG) is deleted.

CEN/TC 392	Cosmetics Chair: Philippe Masson (France) Secretariat: Aurélie Lolia (AFNOR, France)
CEN/TC 392/WG 1	Analytical methods Chair: Gerd Mildau (Germany) Secretariat: Anja Schönenborn (DIN, Germany)
CEN/TC 392/WG 2	Microbiological methods Chair: Joan Thomas (UK) Secretariat: [vacant]
CEN/TC 392/WG 4	Efficacy including sun protection products Chair: Philippe Masson (France) Secretariat: Aurélie Lolia (AFNOR, France)

The task of the WGs is to identify

- which successfully collaboratively tested methods are available;
- which of these give comparable results;
- which of the available methods, if possible one of the comparable ones, is the most appropriate for adoption.

The TC has given the responsibility to the experts of the WGs together with a secretary to elaborate the drafts in a form which complies with the PNE Rules. All meetings are held in English

language (no translation). Technical discussions are only held during the meetings of WGs (physical, usually no telephone or internet conferences), not in the TC, which mainly deals with superior and administrative topics. However, to comply with the Internal Rules of CEN, the TC adopts each draft to be launched for Enquiry or for Formal Vote. Only the TC has secretarial support by professional staff of AFNOR, the French standardization institute, which holds the TC secretariat and has experience in CEN and ISO operational procedures. The CEN/TC 392 meets at least one time per year preferably in the EU. Joint meetings take place with ISO/TC 217 'Cosmetics' when the opportunity presents itself and when ISO/TC 217 meets in Europe. This would be of importance to coordinate the work and avoid any overlap.

The working groups convene when needed and at least once a year before the plenary meeting of CEN/TC 392. The active projects in each WG are not described here but are provided in the work program.

The TC and WGs are supported by members/experts from Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden Switzerland and the United Kingdom. Not all countries are represented in each WG. The technical resources currently available to the working groups include expertise from all stakeholders. These highly qualified experts do not only attend the European meetings, but most of them are also involved in ISO/TC 217. They are also involved in national preparatory meetings in which the expertise of all interested national parties is concentrated.

4.3 Environmental aspects

CEN/TC 392 will address environmental aspects in its standards when these arise.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

The work of the secretariat should be financed by the parties concerned.

Two main factors are identified that play an important role in relation to the timely delivery of the required standards:

- availability of experts;
- availability of funding.

Possible factors affecting the completion and implementation of the CEN/TC 392 work program are that the time and costs for experts (not being a project leader for financed work) are provided by themselves, their employers or their organizations. Experts may have problems with getting allowance from their employers or organizations to participate in the standardization work. Besides this, there can be problems with finding laboratories available to participate in interlaboratory studies due to the time and costs involved to run the analyses.

As CEN target dates are very strict and the work during interlaboratory studies is very unpredictable, delays are not always foreseen.