



# **Challenging Interaction between Evidence-based Scientific Advice and Policy on Consumer Safety**

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# Evidence-based Scientific Advice and Policy on Consumer Safety



- How the evidence-based scientific advice is currently working for consumer safety in Europe
- How the advice is both serving and shaping the policy on consumer safety
- Examples of the challenges faced and how these are being tackled

# The Scientific Committee on Consumer Safety



- Independent SC of the Commission for safety assessment of non-food consumer products (cosmetics, personal-care products, textiles, toys)
- 15 members from 10 countries - Expertise in chemistry, toxicology, exposure assessment, medicine, dermatology, allergies, risk assessment
- Provides scientific advice to the Commission and Guidance for the applicants



# Independence, Scientific Excellence, Transparency & Openness



- A panel of top independent experts in the EU – selected for their excellence in respective fields – all CVs and DoIs published on SC website for free access
- Transparent evidence-based evaluation of safety dossiers to answer mandated questions from the EC – evidence from all available sources assessed critically & thoroughly
- All relevant information made available for free access (except confidential data when requested by companies)
- Draft opinions published and 'commenting period' allowed for questions/comments from all interested parties
- Final opinions published after any necessary revision

# Independence, Scientific Excellence, Transparency & Openness



- All Opinions and information regarding the mandates, meetings, consultations, list of members, etc, published on the SC website for free access
- Factsheets and summaries of some Opinions of direct relevance to the public explaining complicated science in easily understandable terms are also published online
- The SCCS Opinions are highly regarded in Europe as well as in other regulatory jurisdictions across the world
- The stringent regulatory oversight keeps consumers safe, and also boosts credibility of European cosmetics around the world as being safe and reliable

# OUTREACH & DISSEMINATION

Journal articles, Factsheets, Web summaries

All Opinions and information regarding mandates, meetings, consultations, list of members, etc, are freely accessible online



## Keeping Personal Care Products Safe



As consumers, we continually expose ourselves to chemicals through the use of a wide range of personal care products. Many of these products

are used on a daily basis and in different ways. In doing so, we assume that the products meant for enhancing our personal hygiene and appearance will not harm our health.

### → WHO LOOKS AFTER SAFETY OF MY PERSONAL CARE PRODUCTS?

Cosmetic ingredients such as preservatives, colorants, hair colours, UV-filters, fragrances and nanomaterials are specifically controlled under the Cosmetic Regulation in Europe. An independent committee of experts – the Scientific Committee on Consumer Safety (SCCS) – advises the European Commission on the safety of the cosmetic ingredients to support regulatory decisions on whether or not a chemical ingredient should be allowed in cosmetic products, and in which conditions of use.

### → HOW IS IT DONE?

Our skin is the largest exposed surface of the body that protects us by acting as an effective barrier against germs, particles, etc. The skin is, however, not always a good barrier against chemicals, some of which may to some extent not just stay on the skin but be absorbed into the body. Chemicals may also find their way into the body through the mouth or lungs (from some oral hygiene or lip products, or from some spray and aerosol products). Considering the frequent and intimate nature of our contact with personal hygiene and beauty products, the existence

of a rigorous safety overview provides a vital safeguard for the consumer.

The cosmetic safety assessment process is very thorough and takes into account detailed information on the physical and chemical properties of an ingredient, its potential to cause harmful effects, and the consumer exposure from such products. This requires data on possible harmful effects of the ingredients. The assessment particularly aims to exclude any safety risk from hazardous chemicals that may be a CMR (carcinogen, mutagen or reproductive toxin), or may stay and accumulate in the body over time. The assessment of nanomaterials (insoluble or bio-persistent particles on the scale from 1 to 100 nm) may cause different harmful effects compared to the non-particle forms of the chemicals. The safety assessment process also makes sure that a chemical ingredient is sufficiently pure and does not contain unacceptable impurities that could be harmful to consumer's health. The assessment also pays particular attention to certain population groups who may be more vulnerable – such as infants, children and pregnant women, or those who may be more exposed to cosmetic chemicals via their occupation, such as beauty salon staff and hairdressers.

The toxicological testing of chemicals has historically been done on animals. However, testing of cosmetic ingredients on animals, or marketing of a cosmetic product containing ingredients tested on animals, has been banned in Europe since July 2013. Therefore, safety assessments increasingly consider data derived from non-animal models (cultured cells, computational models, etc.).

A positive opinion from the SCCS is only given when the experts have seen sufficient evidence for safety to exclude a risk for consumer's health under foreseen conditions

of the product use. As an example, the European Commission has permitted 100 hair dyes to be introduced on the market and has banned another 180 based on the SCCS advice or due to the lack of required evidence for safety.

It should, therefore, be reassuring to know that a rigorous process for safety assessment and authorisation is in place in Europe before ingredients are allowed to be used in cosmetic products, even though most people don't even think about it. That's the real proof of the trust they place not only in the cosmetic products they purchase and use, but also in the authorities who regulate these products and the manufacturers who produce them.

### → WHERE CAN I FIND MORE INFORMATION?

More information on the work of the SCCS can be obtained at: [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm)

Recent and past scientific opinions of the SCCS can be found at: [https://ec.europa.eu/health/scientific\\_committees/all\\_opinions\\_en](https://ec.europa.eu/health/scientific_committees/all_opinions_en)

This factsheet is based on the Opinions of the Independent Scientific Committee on Consumer Safety (SCCS).

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# Interaction With Policy & Regulation



Based on the scientific advice, the Commission may place an ingredient in one of the Annexes of the of Cosmetic Regulation (EC) No 1223/2009

<b>Annex II</b>	List of prohibited substances
<b>Annex III</b>	List of restricted substances
<b>Annex IV</b>	List of allowed colourants
<b>Annex V</b>	List of allowed preservatives
<b>Annex VI</b>	List of allowed UV-filters

# Challenges to Evidence-based Science & Policy



- Existing Challenges:
  - CMR substances; potential allergens; certain impurities; potential endocrine disruptors.....
- New Challenges:
  - New scientific advancements in techniques, methods & tools (e.g. In silico tools, OMICs)
  - Emergence of novel technologies, materials and applications (e.g. Nanotechnology)
  - Other policy drivers – economic, social, political
  - A change in policy changes the recourse to scientific evidence (Ban on animal testing)



# Example 1: Challenges From Technology Stepping Ahead of Regulation - Nanotechnology



- New form of materials consisting or containing extremely small sized particles (1-100 nanometer)
- Properties, behaviour and effects of nanomaterials may be very different from (normal) chemical forms
- Safety data on chemical forms may not be useful for assessment of nanomaterial safety
- None of the methods for characterisation or toxicity evaluation is yet validated for nanomaterials
- Numerous products are already (or awaiting to be) on the market
- Guidance on safety assessment had been lacking



# Example 1: How the Challenge is Addressed



- A specific working group was set up to look into all available evidence to work out data requirements – produced a detailed Nano Guidance in 2012
- In the absence of validated methods, agreed to accept data from mainstream methods that could be shown to be scientifically-valid for the purpose
- A number of dossiers on nanomaterials since assessed and Opinions published – the first ever assessments of nanomaterials in any regulatory jurisdiction in the world
- Gaps in the safety assessment process identified over time and Guidance updated in October 2019

## Example 2: Challenges From Policy Stepping Ahead of Available Technology – Ban on Animal Testing



- Cosmetic Regulation (EC) No 1223/2009 is the first regulation to have completely banned animal testing of cosmetic ingredients/ products, and marketing of ingredients/products tested on animals in Europe since March 2013
- Safety assessment of cosmetic had historically been based on data from validated animal tests
- Validated in vitro methods are available but do not provide full or quantitative toxicological picture
- Most other methods (in silico models, read-across, OMICs, etc) are not validated yet, and also provide only pieces of evidence needed for safety evaluation

## Example 2: How the Challenge is Addressed

- The SCCS Notes of Guidance were regularly revised – latest version-10 published in December 2018
- Emphasis on the use of alternative methods that may not be validated but can be shown to be scientifically-valid for the purpose
- Emphasis on the need for building an overall weight of evidence from different pieces of the evidence
- Most dossiers so far have relied on using historic animal data (obtained prior to the animal test ban)
- Data from alternative approaches has started to appear in some dossiers
- A complete dossier, based entirely on the data from alternative methods, is awaited.....

# SUMMARY



- Evidence based scientific advice - built around independence, scientific excellence, transparency & openness - works both for consumer safety as well as helps industry to promote safe products
- New challenges arise because either policy or scientific/ technological advancements step ahead of the other – both need to keep pace with each other
- Close interaction between scientific advice and policy with a proactive approach should enable foreseeing any emerging issues, and allow putting in place strategies for tackling them in time.