# Compliance with the European Cosmetics Products Regulation (EC) 1223/2009

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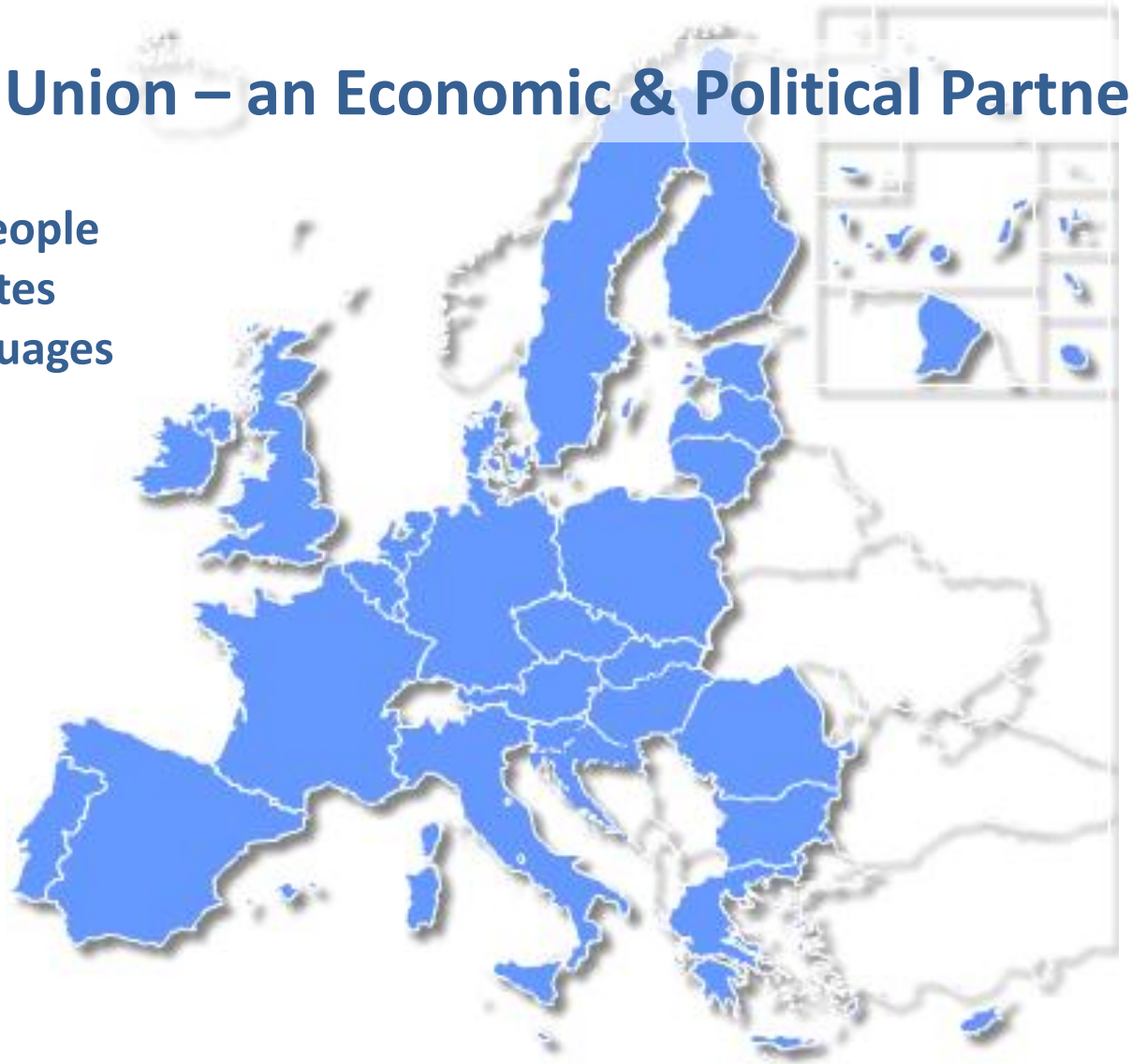
CONUSBAT
Internationalization Regulatory Services

# Areas covered:

- The Recast
- Roles & Responsibilities in the Supply Chain
- Product Information File (PIF)
- Safety Assessment
- Criteria for Claims
- Animal Testing Ban
- Cosmetovigilence
- Substance Regulations
- Product Labeling
- Borderline Legislation /e-Commerce

# The European Union – an Economic & Political Partnership

> 500 Million People
28 Member States
23 Official Languages



# The Internal Market

The internal market is the core of today's European Union and as a consequence people, goods, services and money move around as freely as they do within one country.

# Old European Cosmetics Legislation: DIRECTIVE 76/768/EEC

A Directive has to be translated in national law of the Member States - after 30 years the Cosmetics Directive consisted of:

- The core text with seven amendments and more than 40 technical adaptations
- 27 national legal frameworks and 3500 pages of legal text

# Recasting = Simplification of the EU Cosmetics Legislation

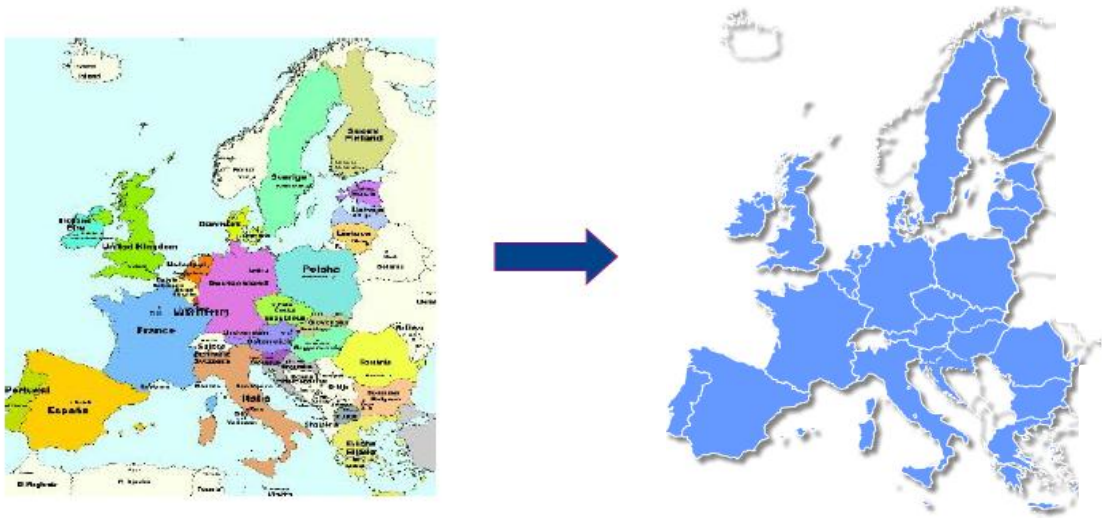
A recast implies modifying existing legislation, while simultaneously bringing all amendments to a given law adopted at different times into one law and in one consolidated text.

# Regulation (EC) 1223/2009 - Implementation Timelines

| | |
|---|---|
| 22 Dec. 2009 | - Publication in Official Journal |
| 11 Jan. 2010 | - Entrance into force |
| 01 Dec. 2010 | - Provisions on use of CMR substances apply |
| 11 Jan. 2012 | - Electronic notification becomes compliant |
| 11 Jan. 2013 | - Notification of nanomaterials applies |
| 11 July 2013 | - All provisions fully apply |
| | - Repeal of the Cosmetics Directive |

# The Recast

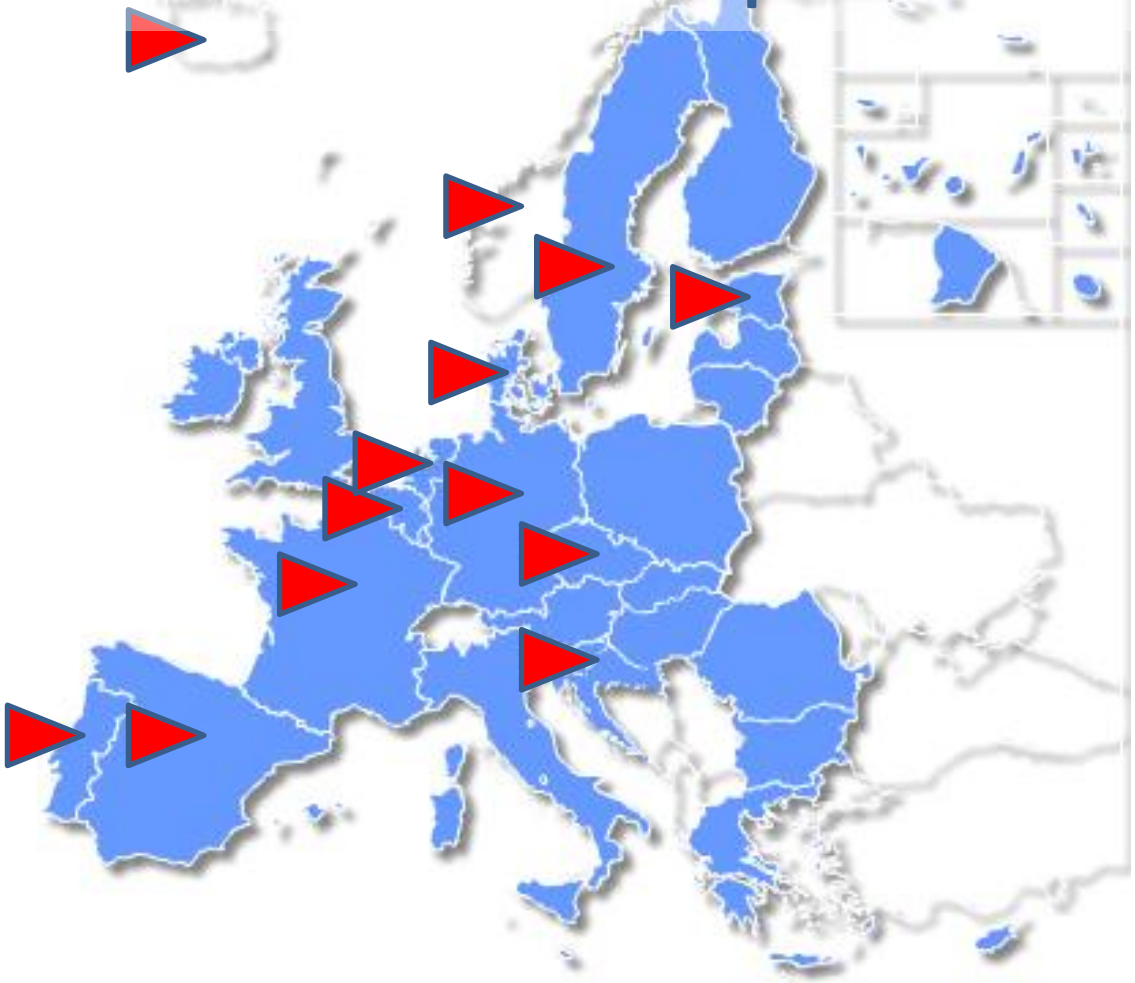
Single piece of legislation which is instantly and directly enforced across the whole EU territory



# Loose Ends

Source: CE

# The Recast – further National Requirements



## Regulation's language versions across the EU are not correct – and the mistakes are not consistent  Creates confusion in the EU and beyond (!)

# Key Results for the Recast

## Remaining Key Pillars

- A wide definition of cosmetic products
- A system of in-market control by EU Member States
- Safety responsibility lies with manufacturers / importers
- Free utilisation of the majority of the substances
- Safety assessment is the main tool for risk prevention

## Areas of Revision

- Clear definitions and assignments of roles and responsibilities
- EU wide, electronic product notifications
- Criteria for Claims
- Reporting of serious undesirable effects
- More detailed requirements for the Safety Assessment
- Substance specific requirements (Nano, CMR)

# Roles & Responsibilities in the Supply Chain

Article 4

(1) Only cosmetic products for which a legal or natural person is designated within the Community as responsible person shall be placed on the market.

# Allocation of Responsibility for Product Safety

Who acts as Responsible Person?

- Generally, a manufacturer or importer established within the EU acts as RP
- They may designate in writing a person within the EU as RP - the person has to accept in writing
- A distributor acts as RP when placing a cosmetic product on the market under his name or trade mark.

# Reg. (EC) 1223/2009 - Roles of Actors in the Supply Chain

## Article 2: Definitions

(d) **manufacturer** means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark

(i) **importer** means any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market

(e) **distributor** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market

# Specific Distributor Obligations

Before making a cosmetic product available on the market distributors shall act with due care and shall verify that:

- the labelling information is present
- the language requirements are fulfilled
  (determined by the Member States law where the product is made available)
- the date of minimum durability has not passed.

- When a doubt about the conformity exists the distributor has to bring the product to conformity before marketing or withdraw marketed products when non-conformity was found.
- In case of identified risks the distributor needs to notify the competent authority.

# Obligations of the Responsible Person

# RP Location

# Product Information File

## Art. 11: Product Information File - Contents

- Product description
- Cosmetic Product Safety Report
- Description of manufacturing method
- Claim substantiation (if applicable)
- Data on animal testing

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# Product Information File

## Article 3

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use.

# Articles Detailing Safety Requirements

- **Art. 3:** A cosmetic product…. shall be safe for human health when used used under normal or reasonably foreseeable conditions of use
- **Art. 10:** …the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a Safety Assessment on the basis of the relevant information and that a Cosmetic Product Safety Report ….. is set up

# Annex I: Cosmetic Product Safety Report

## Part A – Cosmetic Product Safety Information

- Quantitative and qualitative composition of the product
- Physical/chemical characteristics and stability of the cosmetic product
- Microbiological quality
- Impurities, traces, information about the packaging material
- Normal and reasonably foreseeable use
- Exposure to the cosmetic product
- Exposure to the substances
- Toxicological profile of the substances
- Undesirable effects and serious undesirable effects
- (Other relevant) Information on the cosmetic product

# Annex I: Cosmetic Product Safety Report

## Part B – Cosmetic Product Safety Assessment

- Assessment conclusion
- Labelled warnings and instructions of use
- Reasoning (including Margin of Safety [MoS], specific assessment for products intended for children below 3 and for external intimate hygiene products, possible interactions of ingredients, impact of stability on safety)
- Assessor's credentials and approval of part B

## Safety Assessor Qualification

**Art 10(2) A person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine *or a similar discipline*, or a course *recognised as equivalent* by a Member State.**

# Cosmetic Product Safety Report

## Available Commission Guidance

L 315/82 EN Official Journal of the European Union 26.11.2013

**COMMISSION IMPLEMENTING DECISION**

**of 25 November 2013**

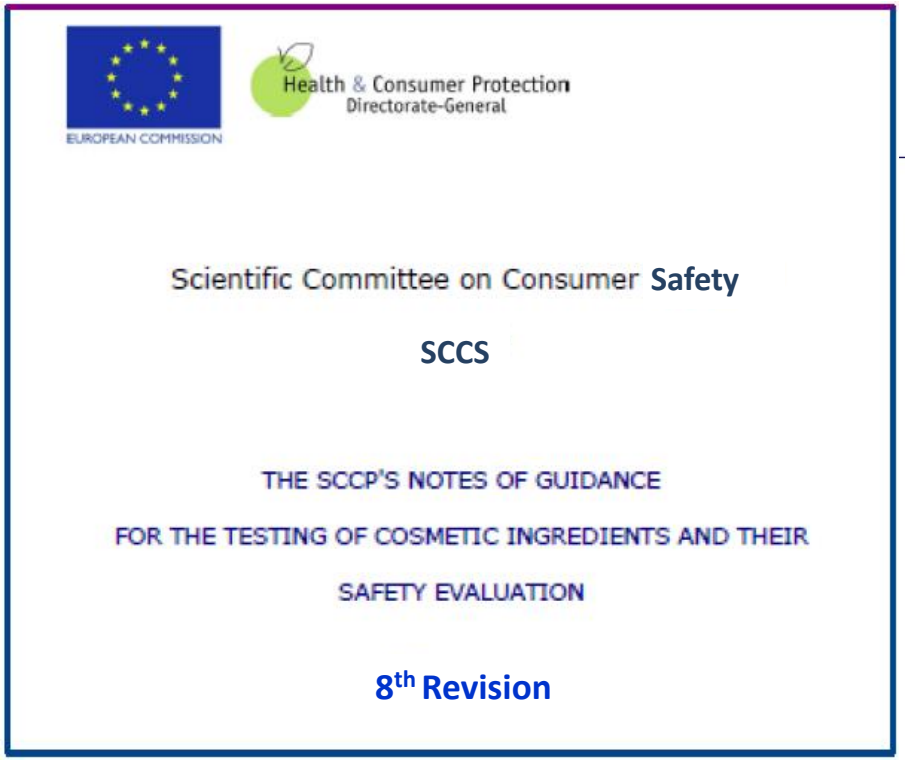
**on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products**

**(Text with EEA relevance)**

(2013/674/EU)

# Cosmetic Product Safety Report

## Available Commission Guidance



EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Consumer Safety

SCCS

THE SCCP'S NOTES OF GUIDANCE

FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR

SAFETY EVALUATION

8th Revision

SCCP/1171/08

European Commission

Scientific Committee on Consumer Safety
(SCCS)

Scientific Committee on Health and Environmental Risks
(SCHER)

Scientific Committee on Emerging and Newly Identified Health Risks
(SCENIHR)

**OPINION ON**

**Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products**

The SCCS/SCHER/SCENIHR adopted this opinion by written procedure on 8 June 2012 after public consultation

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_092.pdf

# Cosmetic Product Safety Report

## Available Commission Guidance

SCCS/1484/12

Scientific Committee on Consumer Safety

SCCS

**GUIDANCE ON THE SAFETY ASSESSMENT OF NANOMATERIALS IN COSMETICS**

The SCCS adopted this opinion at its 15th plenary meeting

of 26 – 27 June 2012

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf

ASt, The Individual Safety Assessment–a Practical Approach towards Regulation (EC) No 1223/2009: http://www.cosmeticsandtoiletries.com/regulatory/region/europe/132196008.html?page=1

**SCCS:** http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

# Product Information File

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# Article 20/CPR: Claims

1. In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have **characteristics or functions which they do not have**.
2. The Commission shall, in cooperation with Member States, establish an **action plan** regarding **claims used** and **fix priorities** for determining common criteria **justifying the use of a claim**.

# Criteria for Claims

11.7.2013 EN Official Journal of the European Union L 190/31

COMMISSION REGULATION (EU) No 655/2013

of 10 July 2013

laying down common criteria for the justification of claims used in relation to cosmetic products

(Text with EEA relevance)

# Regulation (EU) No 655/2013 on Criteria for Claims

1. Legal compliance
2. Truthfulness
3. Evidential support
4. Honesty
5. Fairness
6. Informed decision-making

# Criteria for Claims

1. **Legal compliance**

(1) Claims that indicate that the product has been authorised or approved by a competent authority within the Union shall not be allowed.

(2) The acceptability of a claim shall be based on the perception of the average end user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors in the market in question.

(3) Claims which convey the idea that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements shall not be allowed.

# Criteria for Claims

Version July 2013

**Guidelines to Commission Regulation (EU) No 655/2013**

**laying down common criteria for the justification of claims used**

**in relation to cosmetic products**

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/guide_reg_claims_en.pdf

# Product Information File

## Art. 11: Product Information File - Contents

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# Animal Testing Ban

**Since March 2013, it is prohibited in the EU**

- **To perform animal testing in the EU in order to meet the requirements of the Cosmetics Regulation on finished products and on ingredients and combinations of ingredients**
- **The sales of cosmetic products when either the final formulation or an ingredient has been tested on animals – in the EU or outside of the EU – in order to meet the requirements of the Cosmetics Regulation**

# Animal Testing Ban – Article 18/CPR

## IMPLEMENTATION DEADLINES

| | |
|---|---|
| • Testing ban on finished cosmetic products | 11 Sept. 2004 |
| • Testing ban on ingredients or combination of ingredients | 11 March 2009 |
| • Marketing ban when tested for human health effects with the exception of the specific effects of repeated-dose toxicity, reproductive toxicity and toxicokinetics | 11 March 2009 |
| • Marketing ban when tested on the specific effects | 11 March 2013 |

The ban applies irrespectively on the availability of alternative non-animal tests

# Animal Testing Ban

## EC Interpretation

Source: Cosmetics Europe the personal care association

- Tests performed after March 2013 on ingredients exclusively used in cosmetics trigger ban
- Animal data generated for third country cosmetics regulations can not be used for EU safety assessments
- Use of non-cosmetics data, generated for EU- and non-EU regulatory regimes is allowed
  - Pending interpretation from the European Court of Justice
- No derogative scheme for new cosmetics-unique ingredients

**COMMUNICATION COM(2013) 135 final, Brussels, 11.3.2013**
**http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm**
**In preparation: Guidance on Documentation in the Product Information File in relation to Article 18 (CPR)**

# Status for Animal Test Alternatives - 2014

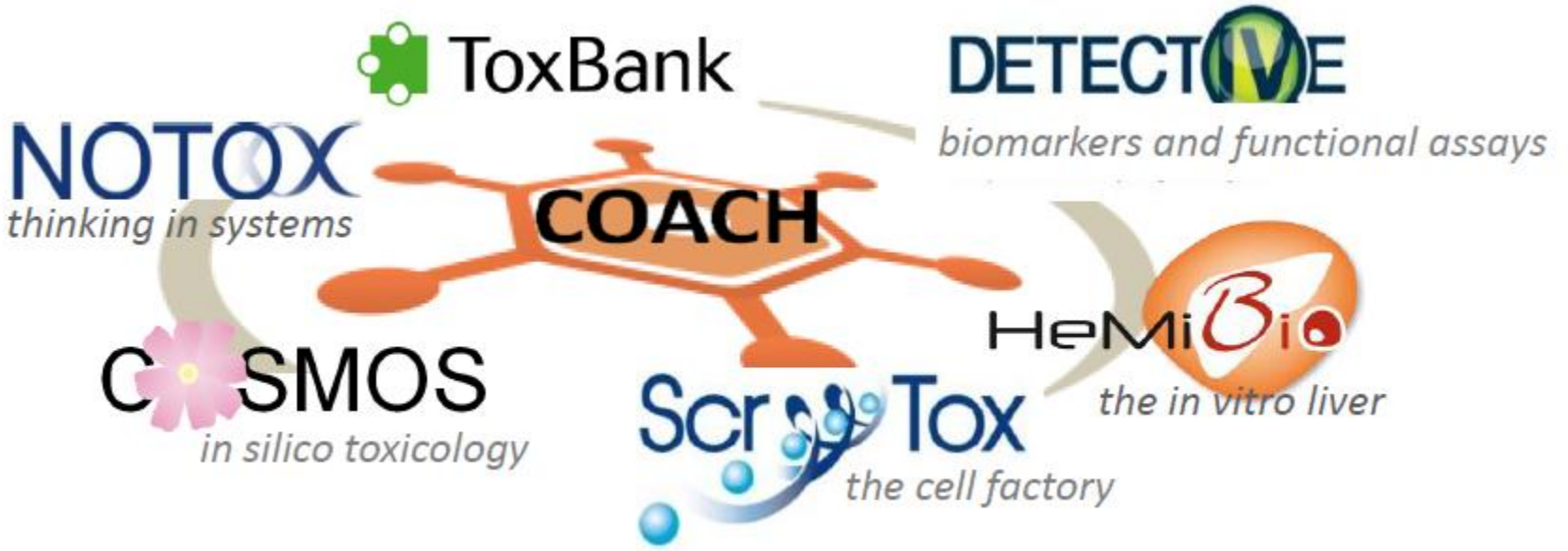
| | |
|---|---|
| Acute toxicity | → Reduction/refinement (oral/inhalation) |
| Skin corrosivity | → Full replacement (TG 430, 431) |
| Skin irritation | → Full replacement (TG 439) |
| Eye irritation | → Partial replacement[1] (TG 437, 438, 460) |
| Skin sensitisation | → No replacement |
| Phototoxicity | → Full replacement (TG 432) |
| Toxicokinetics | → No replacement |
| Repeated dose toxicity | → No replacement |
| Reproduction toxicity | → No replacement |
| Mutagenicity/Genotoxicity | → Partial replacement[2] |
| Carcinogenicity | → No replacement |

Source: CE

[1] Only for compounds causing "serious eye damage" (category 1 of the GHS), or not requiring classification for eye irritation or serious eye damage according to the GHS.
[2] Only for negative results, not possible to follow-up positive/false positive results since animal data would be required.

**T**racking **S**ystem for **A**lternative Test Methods **R**eview:
http://tsar.jrc.ec.europa.eu/index.php?endpoint=3&method=5

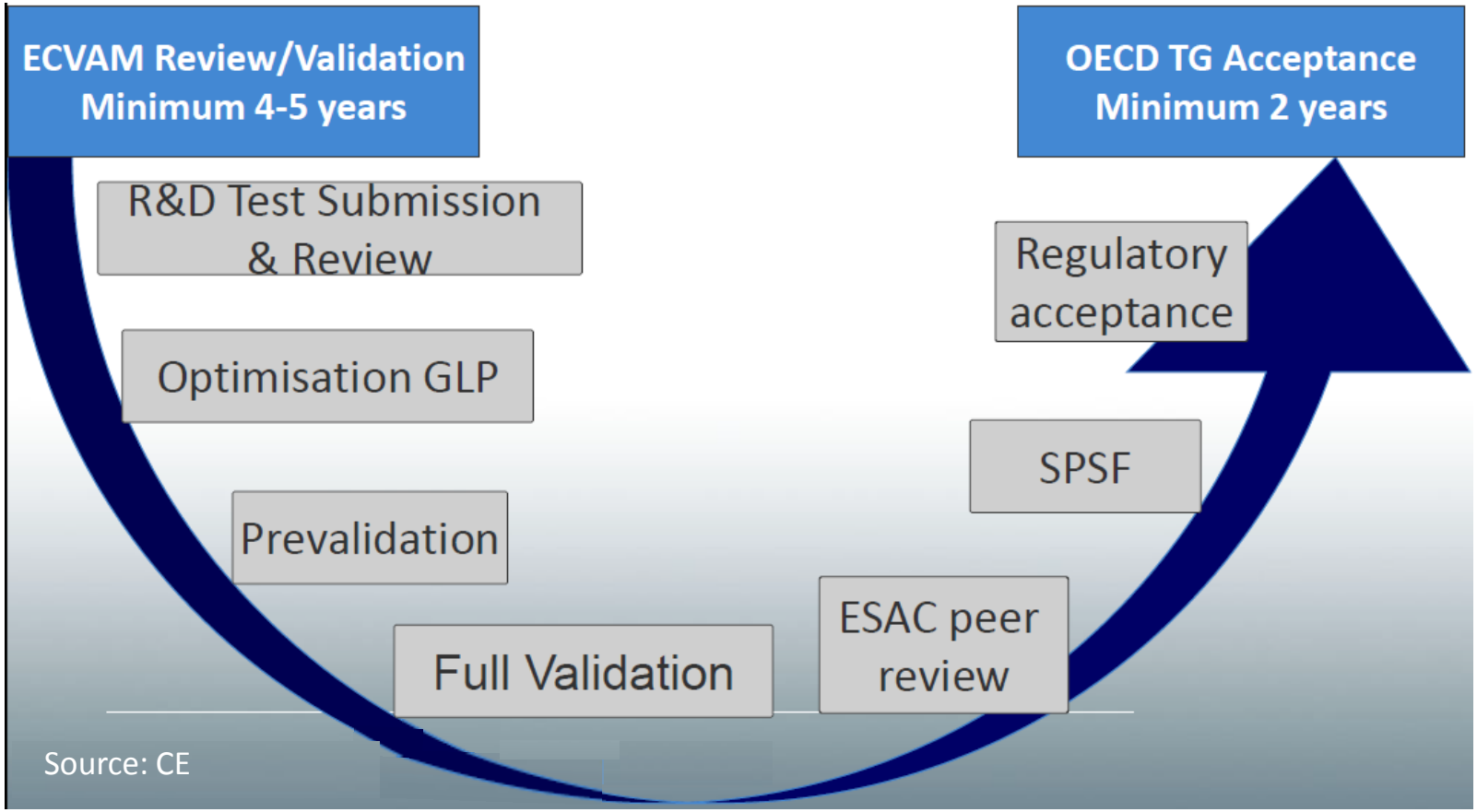
# Research for Animal Test Alternatives



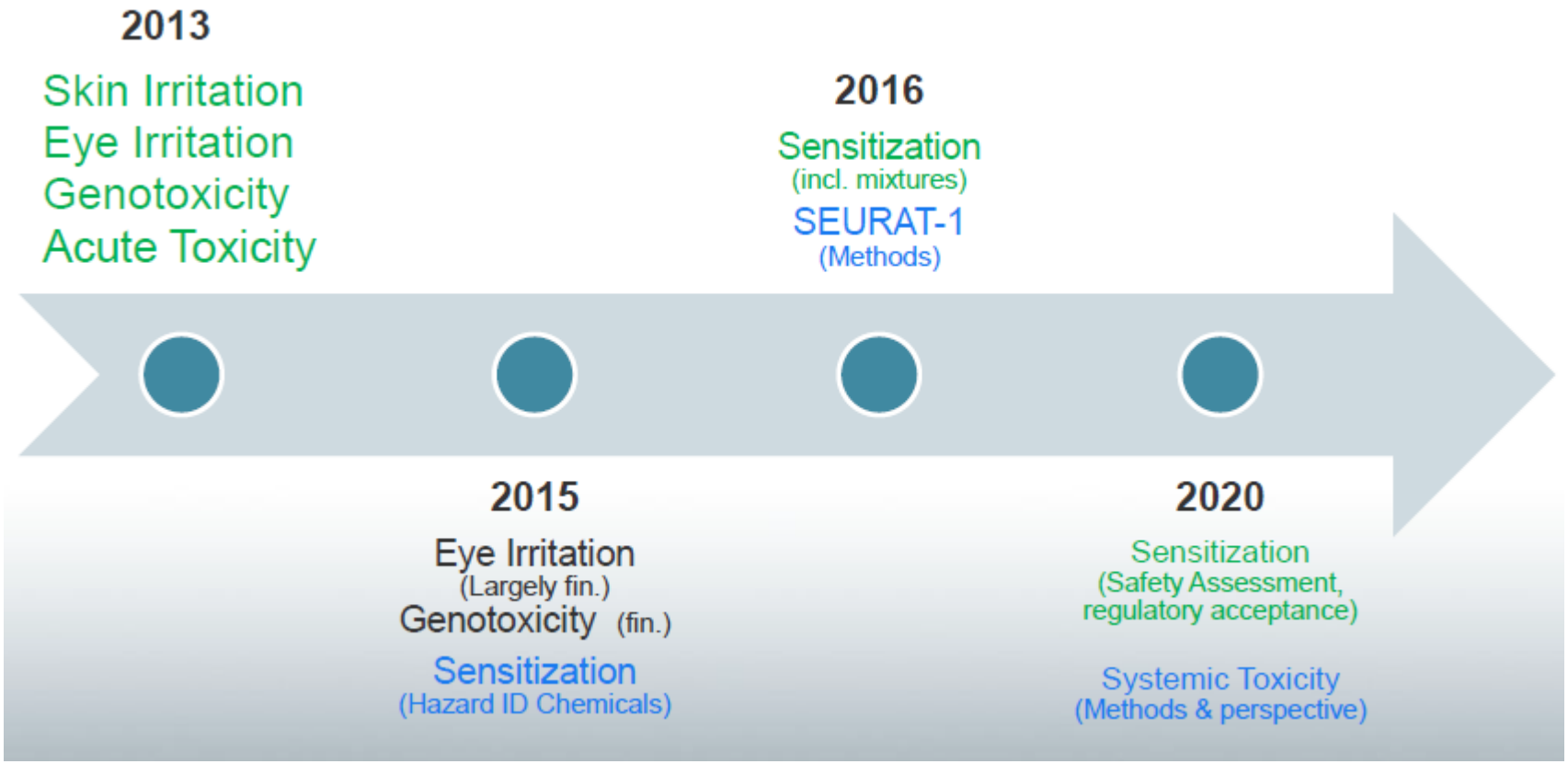

**Seurat-1 is designed as a cluster of seven projects with focus on developing AOP's and proof-of concept integrated safety assessments to replace in vivo repeat dose toxicity testing**

Source: CE

# Test Method Acceptance Process

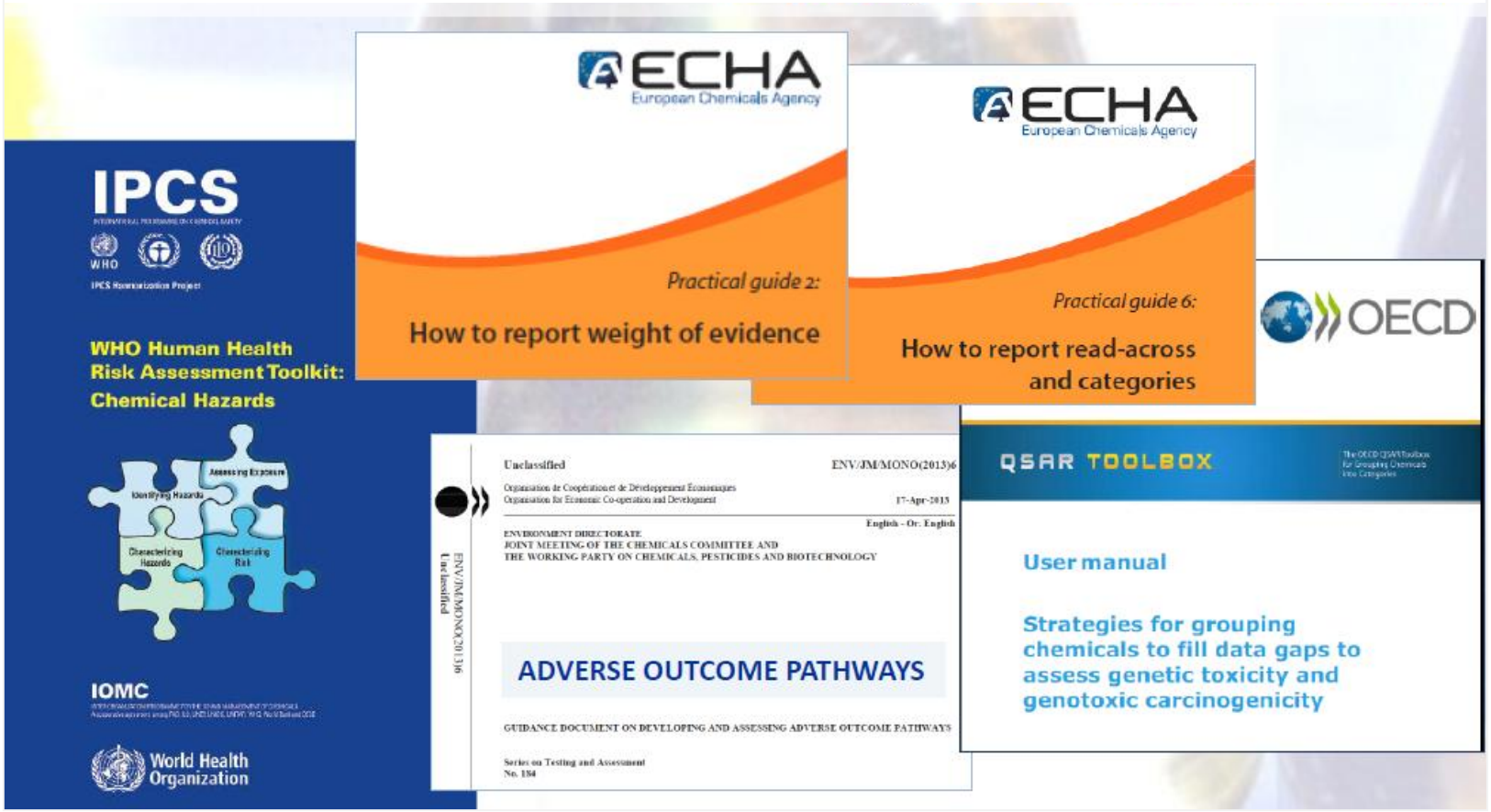


# Roadmap for Alternatives to Animal Tests




Source: Cosmetics Europe

# Alternatives to Animal Testing
## -in-vitro, in-silico, in-chemica methods



# ANIMAL TESTING

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics**

> In order to allow effective market surveillance, responsible persons should ensure that for any animal testing data relied on in the product information file the date and place of the test is clearly documented. If testing took place after the 2013 marketing ban deadline, the product information file should allow verification on whether the testing was carried out in order to meet the requirements of the Directive/Regulation or for other purposes. To this end the file should contain documentation on any use of the substance in products other than cosmetic products (product examples, market data etc.), as well as documentation on compliance with other regulatory frameworks (e.g. REACH or other legal frameworks) and a justification of the need for the animal testing under that other framework (e.g. testing proposal under REACH).

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf

# Summary: PIF & Cosmetic Product Safety Report

No totally new elements have been introduced, however:

- the description of requirements is more detailed and more specific
- the safety assessment is requested in writing (CPSR), but without a defined format
- a comprehensive approach is requested (Annex I, Part A)

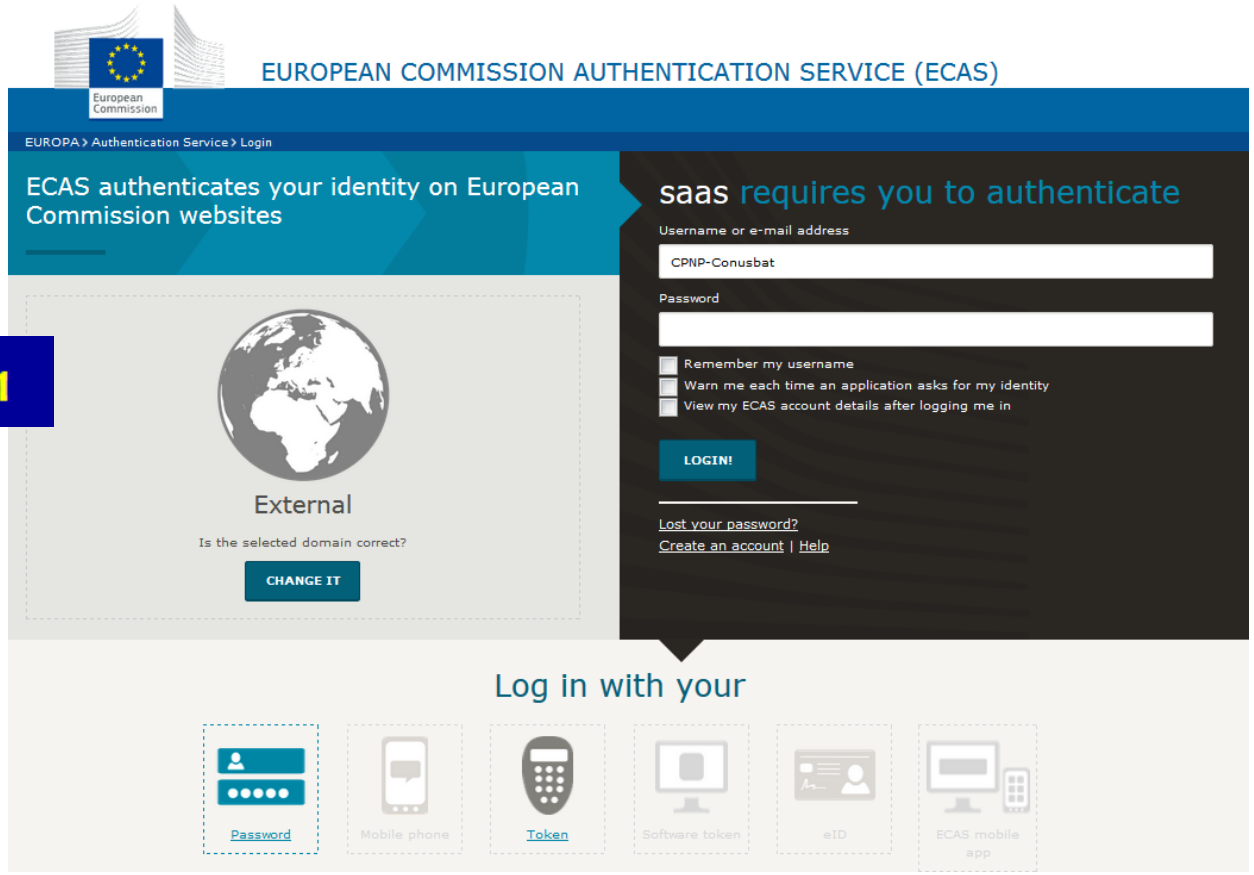
# Product Information File - Article 11

PIFs need to be updated when necessary, to be kept for 10 years after the last batch placed was on the market, the language needs to be easily understood by the competent authorities of the relevant Member States.

# Cosmetic Product Notification Portal - CPNP

CPNP Cosmetic Products Notification Portal

http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/index_en.htm
https://webgate.ec.europa.eu/aida/selfreg




Step 1

# Notification under the new Cosmetics Product Regulation

- Central, electronic notifications at EU Commission level
- The Commission makes the information available to Member State Competent Authorities
- The Commission makes the information available to Poison Centres or similar institutions in the Member States

# In-market Control

European Commission

GROWTH

Internal Market, Industry, Entrepreneurship and SMEs

## Market Surveillance

**EU countries are responsible for the surveillance of their own markets for cosmetics. In order to ensure a coherent approach to consumer products issues, the market surveillance authorities of all EU countries established the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC).**

### Guidelines

To facilitate the implementation of the Cosmetics Regulation and to establish a harmonised communication and management system on SUE throughout the EU, the Commission, in cooperation with EU countries and industry, established special guidelines. The aim of these guidelines is to help ensure harmonised notification of SUE by the responsible person or distributor, and to ensure that SUE notifications are followed-up by national authorities, responsible persons, or distributors.

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/index_en.htm

# Cosmetovigilence

- Serious undesirable events (SUE) – definition & reporting
- PIF Documentation
- Access to information for the public

# Communication of Serious Undesirable Effects

**Pharmacovigilance:** The pharmacological concept of collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The central body is the physician.

**Cosmetovigilance:** Translation of the concept into the cosmetic sector with the Responsible Person as the central body.

# SUEs

**Article 2(p):** «Serious undesirable effect» means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies, or an immediate vital risk or death.

# Communication of Serious Undesirable Effects

## SUE Reporting Guidelines - July 2013*

### Containes three Reporting Form Sheets

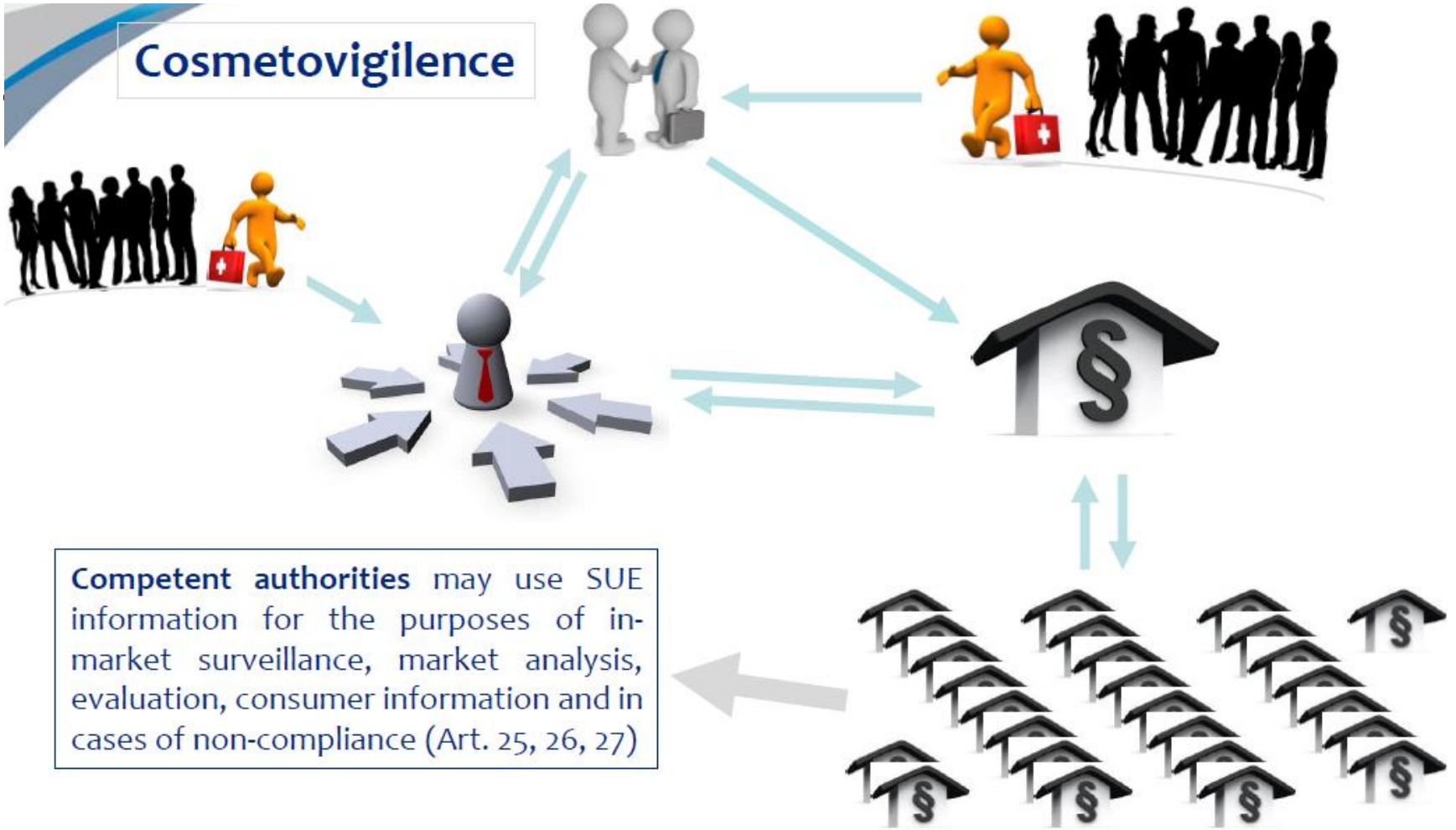
SUE Form A: Responsible Persons or Distributors notifying SUEs to the Competent Authorities

SUE Form B: This form is completed by the Competent Authority and attached to SUE Form A to provide a brief summary and perspective of the case when the Competent Authority transmits SUE Form A to other Competent Authorities and to the Responsible Person. The transmission to the Responsible Person is mandatory when the initial notification comes from a Distributor.

SUE Form C: Competent Authorities transmitting SUEs reported by health professionals or end users to other Competent Authorities and the Responsible Person.

* http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/index_en.htm

# Cosmetovigilence



**Competent authorities** may use SUE information for the purposes of in-market surveillance, market analysis, evaluation, consumer information and in cases of non-compliance (Art. 25, 26, 27)

# Non-Compliance

Article 25: Competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit.

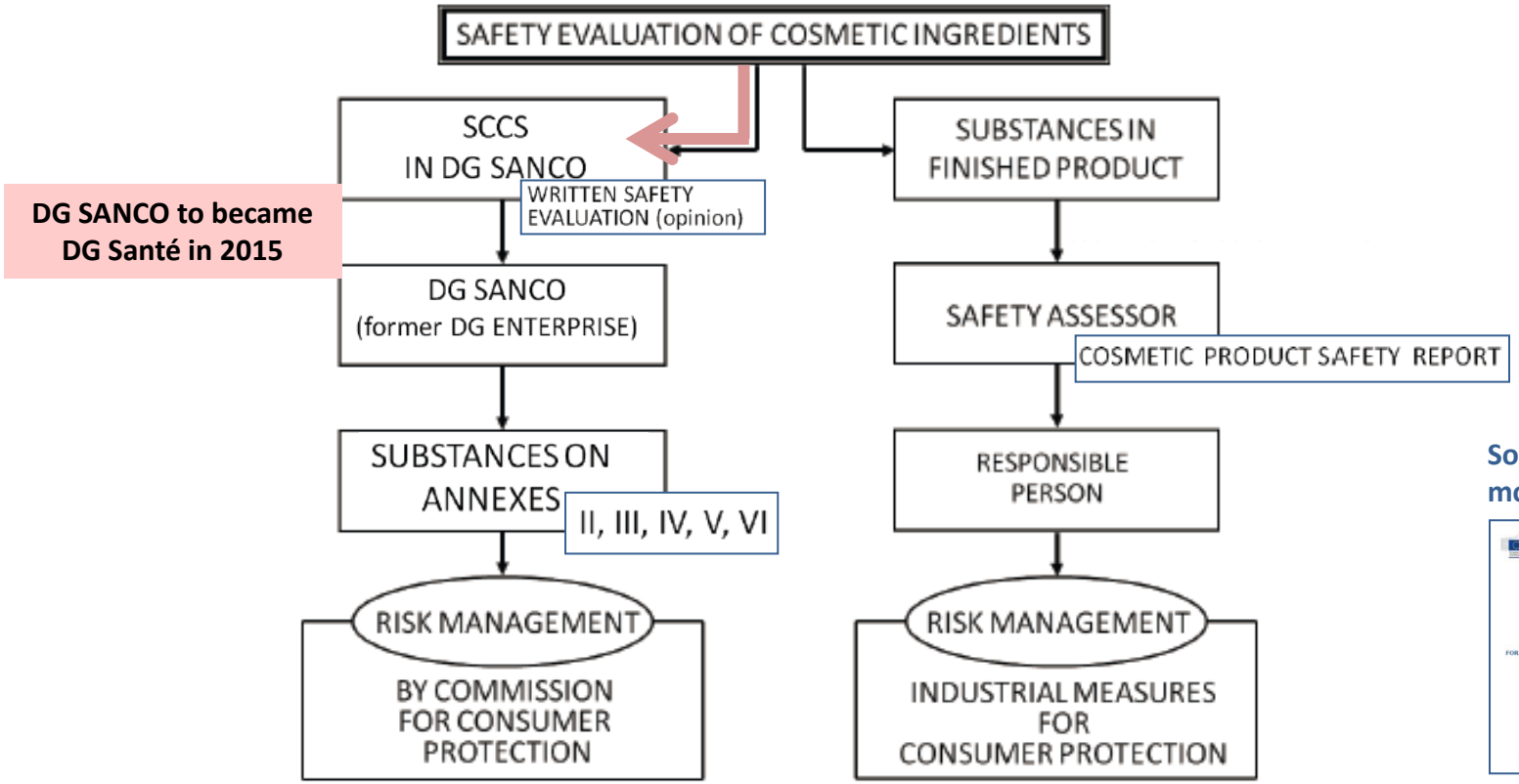
## Substances Regulations

- **The Dual Approach towards Cosmetic Ingredients' Safety in Use:**

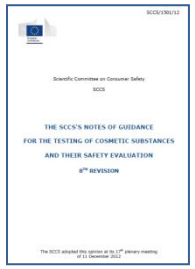
**Safety assessment performed by a scientific committee of the EU Commission.**

**Individual safety assessment which has to be performed by product manufacturers on those ingredients with no regulatory restrictions imposed.**

# The Dual Approach towards Cosmetic Ingredients' Safety in Use:

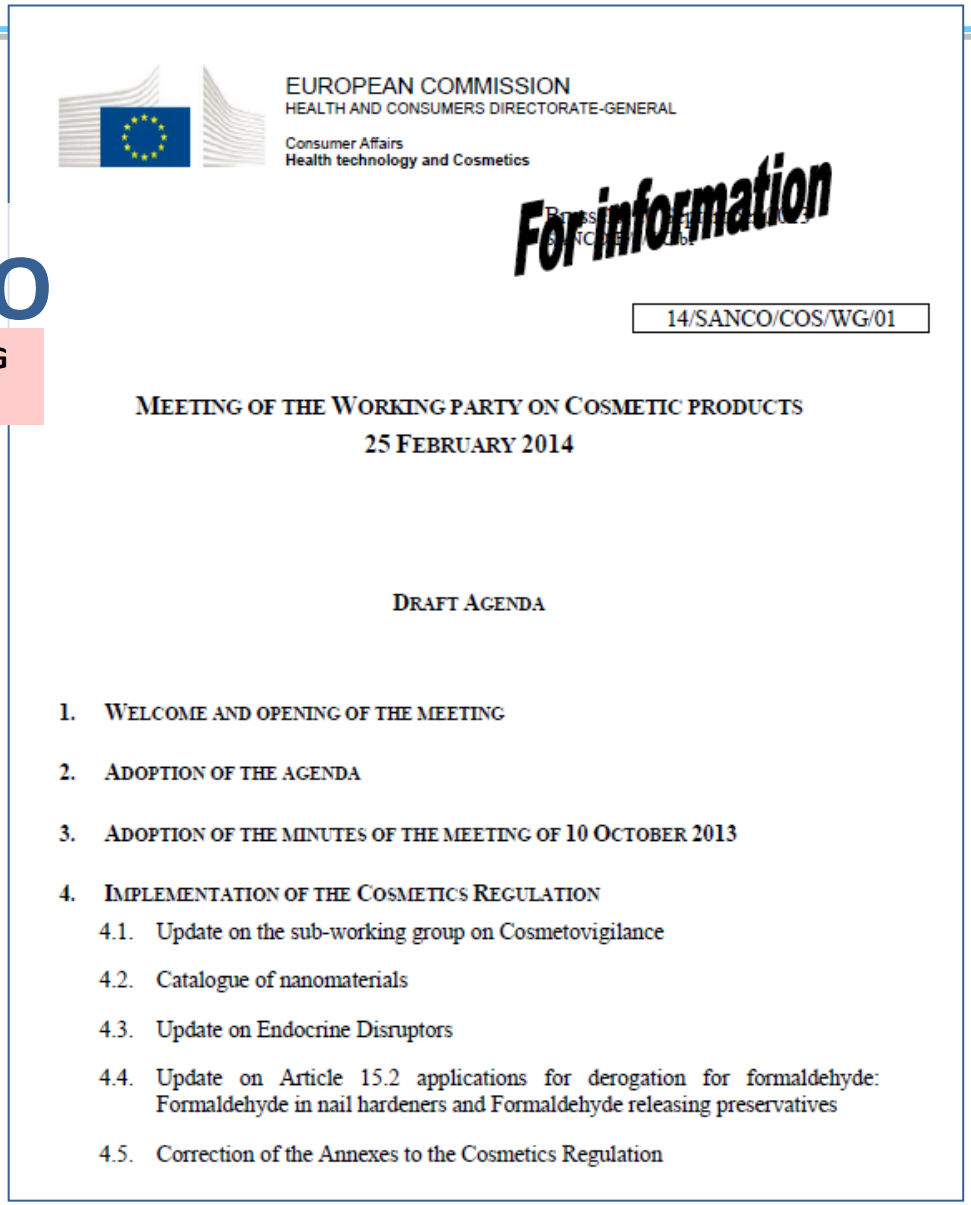



**Source – modif. graph:**



# DG SANCO

**DG SANCO to became DG Santé in 2015**



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Consumer Affairs
**Health technology and Cosmetics**

**For information**

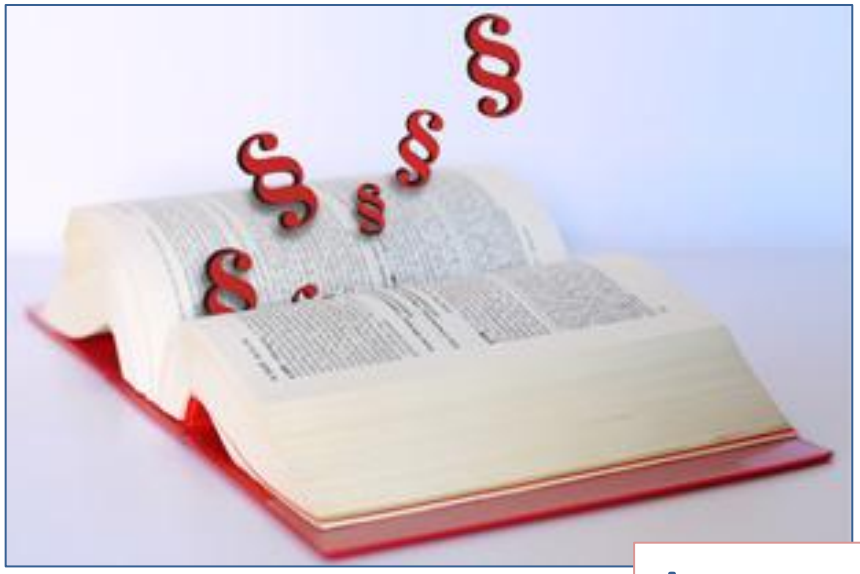
14/SANCO/COS/WG/01

MEETING OF THE WORKING PARTY ON COSMETIC PRODUCTS
25 FEBRUARY 2014

DRAFT AGENDA

1. WELCOME AND OPENING OF THE MEETING
2. ADOPTION OF THE AGENDA
3. ADOPTION OF THE MINUTES OF THE MEETING OF 10 OCTOBER 2013
4. IMPLEMENTATION OF THE COSMETICS REGULATION
   - 4.1. Update on the sub-working group on Cosmetovigilance
   - 4.2. Catalogue of nanomaterials
   - 4.3. Update on Endocrine Disruptors
   - 4.4. Update on Article 15.2 applications for derogation for formaldehyde: Formaldehyde in nail hardeners and Formaldehyde releasing preservatives
   - 4.5. Correction of the Annexes to the Cosmetics Regulation

# The Law



Annexes II, III, IV, V, VI

# Substances Regulations

ANNEXES

ANNEX I - **COSMETIC PRODUCT SAFETY REPORT**

ANNEX II - **LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS**

ANNEX III - **LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN**

ANNEX IV - **LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS**

ANNEX V - **LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS**

ANNEX VI - **LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS**

ANNEX VII - **SYMBOLS USED ON PACKAGING/CONTAINER**

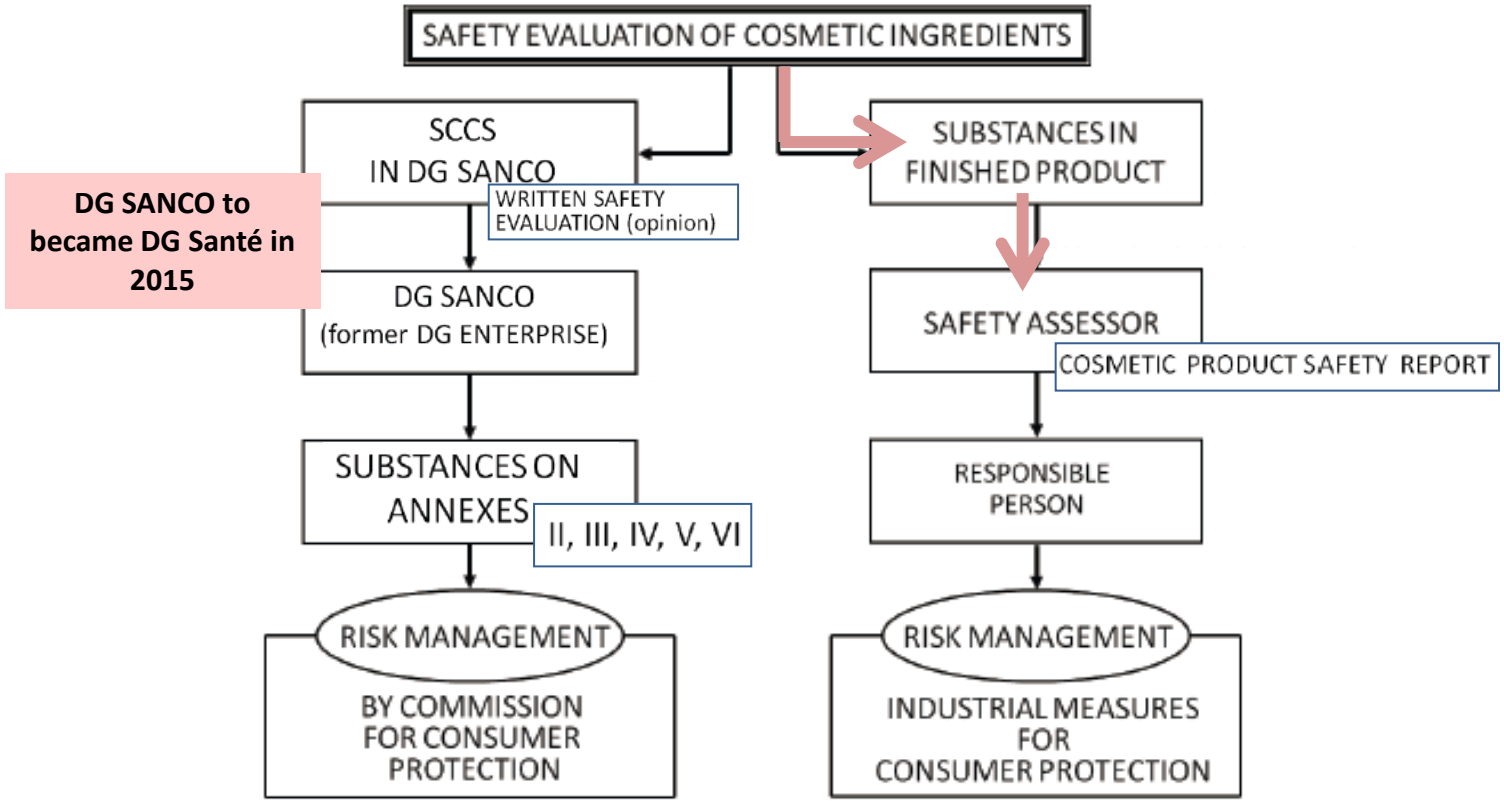
ANNEX VIII - **LIST OF VALIDATED ALTERNATIVE METHODS TO ANIMAL TESTING**

ANNEX IX - PART A: **Repealed Directive with its successive amendments**

PART B: **List of time-limits for transposition into national law & application**

ANNEX X - **CORRELATION TABLE**

- **The Dual Approach towards Cosmetic Ingredients' Safety in Use:**



- The Individual Safety Assessment

# Annex I: Cosmetic Product Safety Report

**Part A – Cosmetic Product Safety Information**

- Quantitative and qualitative composition of the product
- Physical/chemical characteristics and stability of the cosmetic product
- Microbiological quality
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**Part B – Cosmetic Product Safety Assessment**

- Assessment conclusion
- Labelled warnings and instructions of use
- Reasoning (incl. Margin of Safety [MoS], specific assessment for products for children < 3 and for external intimate hygiene, possible interactions of ingredients, impact of stability on safety)
- Assessor's credentials and approval of part B

# Summary on Substances' Evaluation

**Responsibility for the safety in use lies with the cosmetic product manufactures.**

**A large number of ingredients are regulated in 5 Annexes to the Cosmetic Product Regulation, however, the majority of ingredients is free to use.**

**The approach towards evaluation of the ingredients safety is a dual approach - regulated substances are evaluated by an expert panel at governmental level, non regulated substances need to be assessed by an expert of the cosmetic product manufacturer.**

## Substance Specific Requirements

# CMRs – Use Conditions (Article 15)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 is prohibited.

However, such substances may be used in cosmetic products by way of exception where:

- they comply with the food safety requirements
- there are no suitable alternative substances available
- the application is made for a particular use of the product category
- they have been evaluated and found safe by the SCCS

# REACH - Preamble 13

This Regulation should apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC* of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products in so far as substances are used and marketed as cosmetic ingredients and are within the scope of this Regulation. A phase-out of testing on vertebrate animals for the purpose of protecting human health as specified in Directive 76/768/EEC* should take place with regard to the uses of those substances in cosmetics.

*now Regulation (EC) 1223/2009

# Nanomaterials, CMRs, Hair Colorants

# Substance Specific Requirements

## Nanomaterials

### Current definition of a nanomaterial:

Nanomaterial » means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

# Substance Specific Requirements

## Requirements for Nanomaterials (Article 16)

In addition to the general notification requirements, products containing nanomaterials need to be notified six months prior to placing on the market, providing the following information:

- identification of the nanomaterial including its chemical name (IUPAC) and other descriptors
- the specification of the nanomaterial including size of particles, physical and chemical properties
- an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year
- the toxicological profile of the nanomaterial
- the safety data of the nanomaterial relating to the category of cosmetic product
- the reasonably foreseeable exposure conditions.

Important: The provisions do not apply to nanomaterials used as colorants, UV-filters or preservatives.

## Substance Specific Requirements

# Labelling of Nanomaterials - Article 19

All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Titanium Dioxide (Nano)

# Substance Specific Requirements

SCCS/1484/12

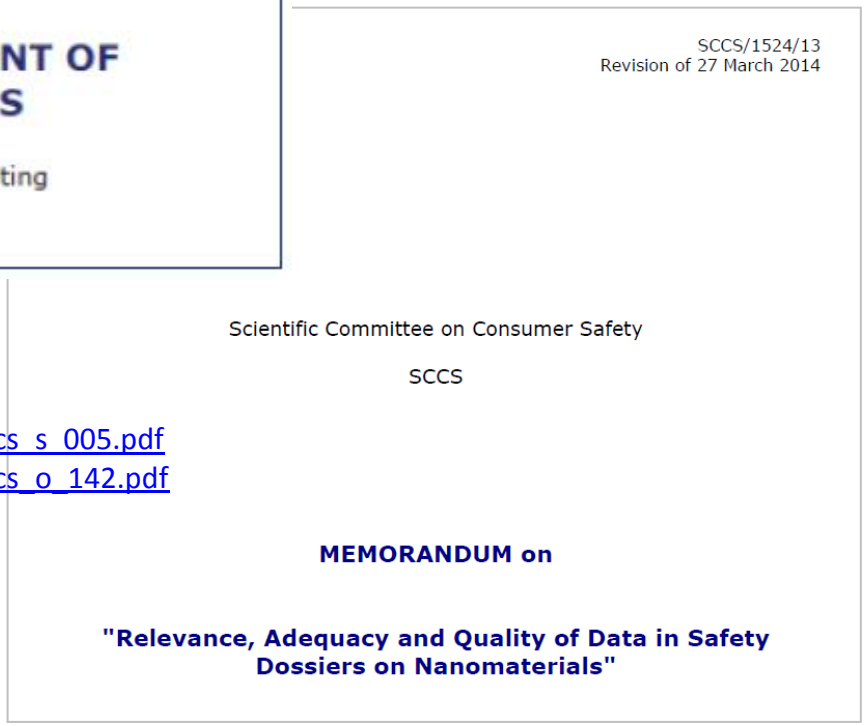
Scientific Committee on Consumer Safety

SCCS

**GUIDANCE ON THE SAFETY ASSESSMENT OF NANOMATERIALS IN COSMETICS**

The SCCS adopted this opinion at its 15th plenary meeting

of 26 – 27 June 2012



SCCS/1524/13
Revision of 27 March 2014

Scientific Committee on Consumer Safety

SCCS

**MEMORANDUM on**

**"Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials"**

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_142.pdf

## Substance Specific Requirements

# CMRs – Use Conditions (Article 15)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 is prohibited.

However, such substances may be used in cosmetic products by way of exception where:

- they comply with the food safety requirements
- there are no suitable alternative substances available
- the application is made for a particular use of the product category
- they have been evaluated and found safe by the SCCS

## Substance Specific Requirements

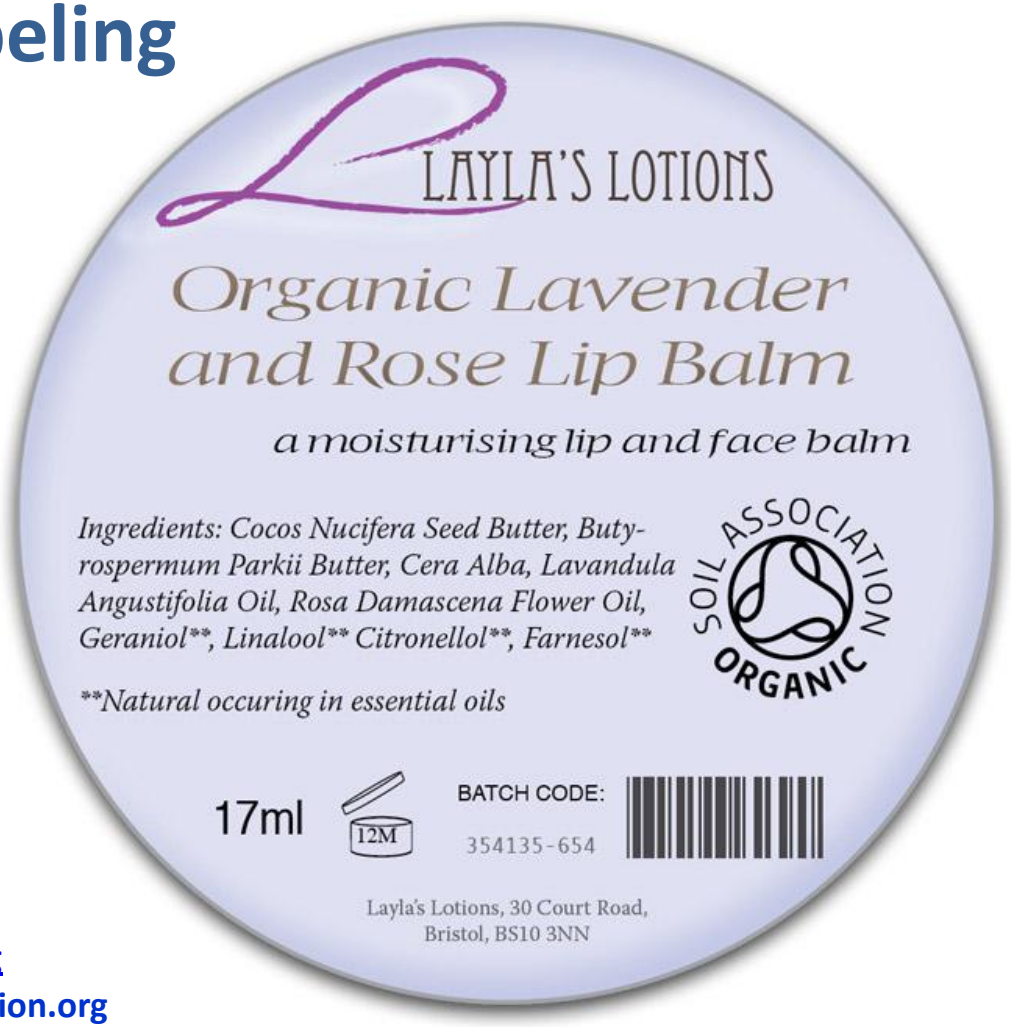
# Hair Colorants

### Article 2: Definition

(m) 'colorants' means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, **precursors of oxidative hair colorants shall be deemed colorants**.

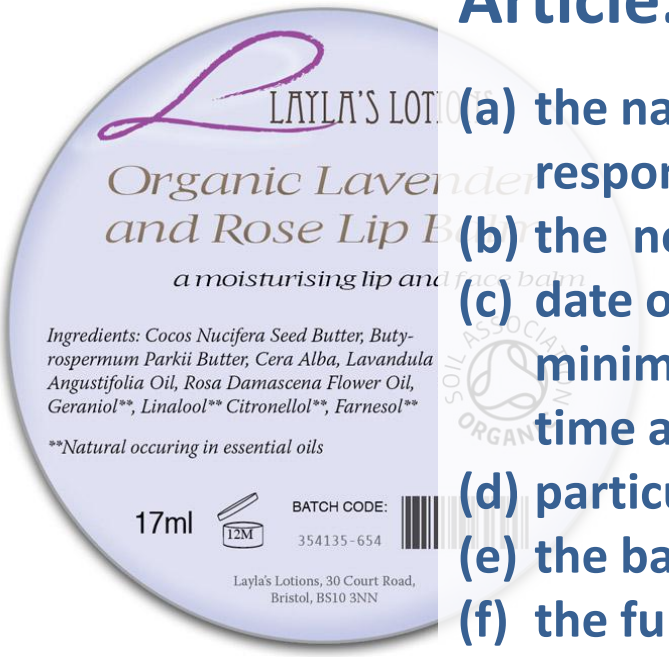
>> As a consequence hair colorants have to be listed in Annex IV: LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS

# Product Labeling




[CPR - Article 19: Labelling]

**Label source: soilassociation.org**




# Article.19 (1): Labelling

(a) the name or registered name and the address of the responsible person
(b) the nominal content at the time of packaging
(c) date of minimum durability or for cosmetic products with a minimum durability of more than 30 months the period of time after opening
(d) particular precautions to be observed in use
(e) the batch number
(f) the function
(g) a list of ingredients

Label source: soilassociation.org

# Borderline Legislation

Borderline is a product when it is unclear whether it is a cosmetic, resp., a detergent product in the sense of the cosmetics, resp., the detergent regulatory frameworks or whether it falls under other sector legislation. This decision is to be taken on a case-by-case basis.



**Guidance:**
**MANUAL ON THE SCOPE OF APPLICATION OF THE COSMETICS REGULATION (EC) NO 1223/2009 (ART. 2(1)(A)) - VERSION 1.0 (NOVEMBER 2013)**
http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/docs/manual_borderlines_ol_en.pdf

**EU Commission – Pages on Cosmetics:**
http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/index_en.htm
http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm

# Summary

- Responsibility for the safety in use lies with the cosmetic product manufactures.
- In-market control by Member State authorities.
- Cosmetovigilence system with a central RP.
- PIF: Key tool for safety and general legal compliance.
- Label: Legal document for consumer information.
- Dual approach towards evaluation of the ingredients safety.
- Defined ingredients are regulated in 5 Annexes to the CPR.
- The majority of ingredients is free to use but must be individually assessed for their safety.
- Further specific provisions exist for defined ingredient groups.
- Animal Testing Ban fully implemented.
- Central notification prior to marketing.

# CONUSBAT

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