Collegio Europeo di Parma

Seminar on:
"EU Cosmetics Policy"
2019

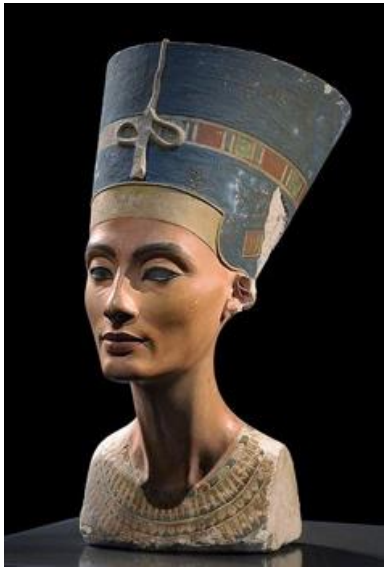
Thursday 11 April 2019

Location: Collegio Europeo di Parma, Via Università 12, Parma

11:00 - 12:30	***EU Cosmetics Law and Policy*** Prof. Patrick Deboyser

The EU Cosmetics Market

- Humans have used cosmetics for thousands of years.
- Today, Europeans use on average **seven** different cosmetic products per day such as:
  - Hygiene products: **soap, shampoo, toothpaste, deodorant**
  - Beauty products: **perfumes, make-up, hair colours**



- Valued at €77.6 billion at retail sales price in 2017, the **European market** for cosmetics and personal care products is the largest in the world.
- There were **4 605 SMEs** manufacturing cosmetic products in Europe in 2015.
- It is also a very dynamic sector: each year, about 25 % of cosmetic products on the European market are new.

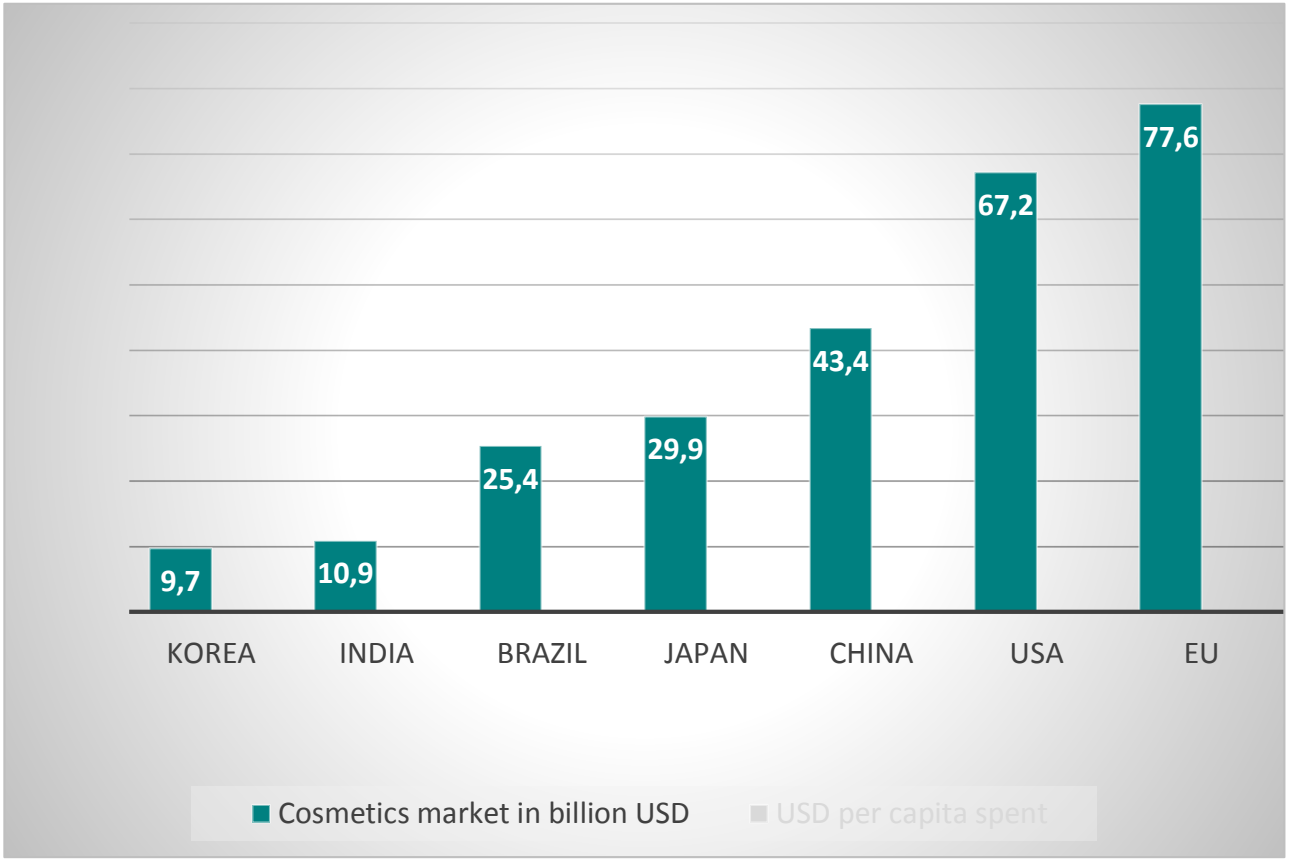
The EU Cosmetics Market

- Including direct, indirect and induced economic activity, the industry supports **over 2 million jobs**. 165,750 people are employed directly, and a further 1.64 million indirectly in the cosmetics value chain.

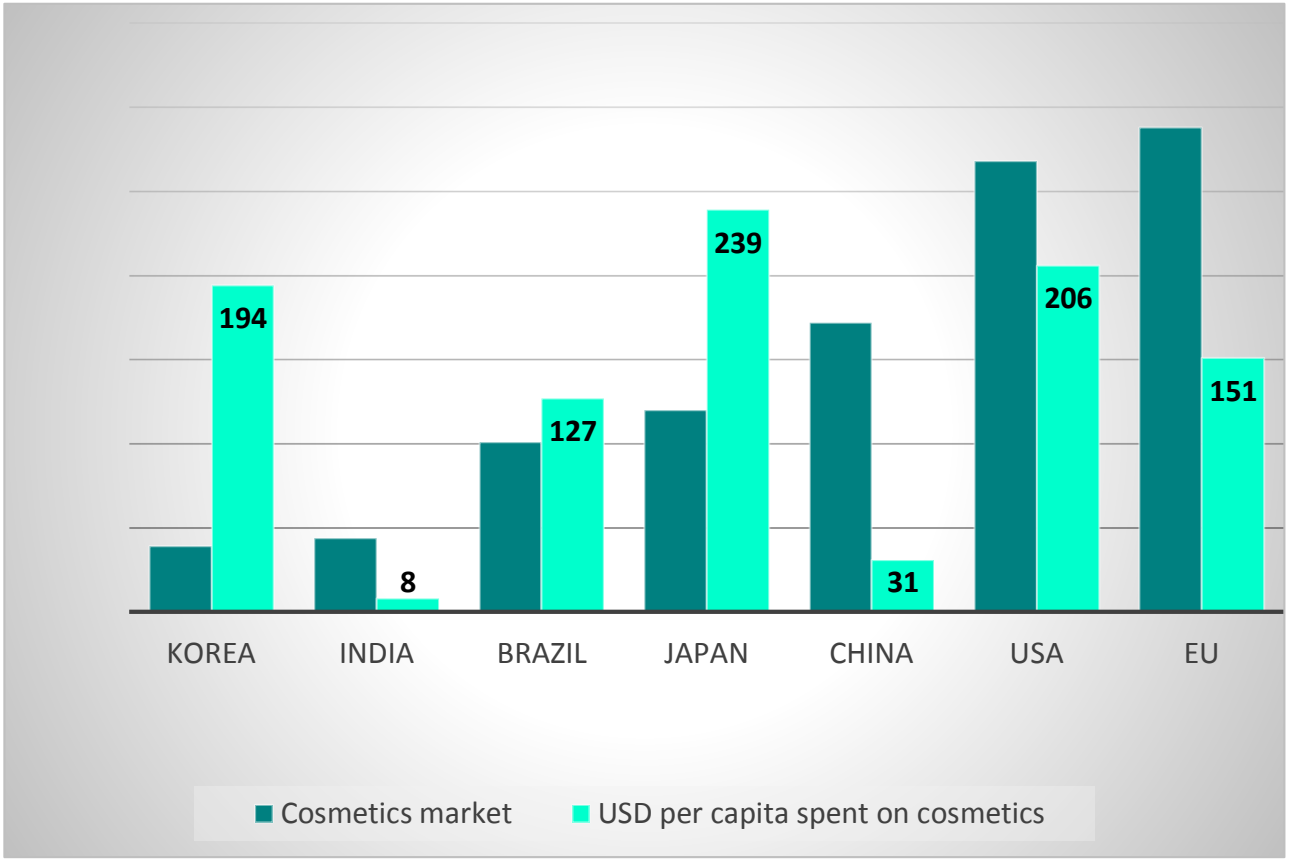
165,750 workers employed in the manufacture of cosmetics

- The cosmetics and personal care industry is a science-driven and **highly innovative sector** which makes large investments in R&D. It can take over 5 years of research and formulation to bring a new product to the market. A large proportion of **patents** granted in the EU are for the cosmetics industry products (e.g. 10% of all patents awarded in the EU in 2009).

The Global Cosmetics Market



The Global Cosmetics Market



EU Harmonisation

- In the early 1970's the EU decided to **engage harmonisation** work in the cosmetics sector in order to enable the free circulation of cosmetic products within the Community. standards.

Directive 76/768/EEC

- The **Cosmetics Directive** was adopted in 1976.
- It was **amended** seven times and its **Annexes** updated to technical progress more than 50 times. In 2008, the European Commission presented a **proposal** aiming at modernizing and simplifying the Ditrective.

Regulation 1223/2009

- The EU Council and Parliament adopted the **Cosmetics Regulation** in 2009, which entered into force in 2013.

Key principles (1)

- **No pre-market registration or certification of products**
  - The Cosmetics Regulation establishes an **in-market control** system rather than a pre-market approval procedure.
  - It is **the responsibility of the person (RP)** who places the cosmetic product on the market to ensure that the product is safe and meets all the requirements of the Cosmetics Regulation
- **Product must be safe and safety must be demonstrated**
  - Some ingredients are banned (negative list)
  - Some ingredients can only be used if they are authorized (positive lists)
  - The use of certain ingredients is restricted or subject to conditions
  - Some ingredients have additional regulatory requirements
- **Animal testing and alternative methods**
  - The Cosmetics Regulation provides the regulatory framework for the phasing out of animal testing for cosmetics purposes.

Key principles (2)

- **Products must be notified prior to placing on the market**
  - The Cosmetics Regulation replaces all national product notification schemes by single, central electronic notification requirement at the European Commission.
- **Adequate and non-misleading information must be provided**
  - Products must be labelled in accordance with the Cosmetics Regulation;
  - Misleading advertising is prohibited and claims are regulated.
- **Post-market Surveillance and Cosmetovigilance**
  - Post-market controls of compliance are performed by Member States competent authorities.
  - Undesirable effects must be monitored.

Responsible person (RP)

- The Regulation requires the designation, in the European Union, of a **Responsible Person (RP)** for every cosmetic product placed on the EU market.
- The RP must take **responsibility** to ensure that every cosmetic product placed on the market **complies** with all the requirements of the Regulation.
- Once the product has been put on the market, if any questions about its **safety**, its **packaging** or its **labelling** arise, the RP will be considered liable.
- The Responsible Person may be a **natural** or a **legal** person. His name and address must be printed on the primary (container) and secondary packaging of each product for which he takes responsibility.

Product Information File (PIF)

- The **Responsible Person** must:
  - establish and maintain a **Product Information File (PIF)** for all products, including imported, professional, promotional gifts;
  - keep the PIF **accessible to the authorities** to demonstrate that the product meets the requirements of the Cosmetics Regulation;
  - ensure that a **safety assessment** has been performed for each product by a qualified Safety Assessor – and updated when necessary.

Safety Assessor (SA)

- The **Safety Assessor (SA)** is responsible for assessing the safety of a cosmetic product.
- His/her qualifications are defined in the Regulation:
  - 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.

Ingredient management

Overview

- The choice of safe ingredients is in the responsibility of the Responsible Person (and his **safety assessor**)
- For some classes of ingredients, however, the EU has identified the need to introduce **harmonised restrictions**.
- These restrictions are **science based** and established through a transparent review mechanism involving the **Scientific Committee on Consumer Safety – SCCS**.
- Regulated ingredients fall under 4 categories:
  - Prohibited substances (negative list)
  - Ingredients can only be used if they are authorized (positive lists)
  - Ingredients the use of which is restricted or subject to conditions
  - Ingredients to which additional regulatory requirements apply

Ingredient management

Prohibited substances

- **Annex II** of the EU Cosmetics Regulation lays down the list of substances **prohibited** in cosmetic (negative list).
- The list contains the **substance identification** (Chemical name/INN, CAS Number and EC number) of each prohibited substance and currently includes **1382** substances.

File creation date: 09/04/2019

ANNEX II, Last update: 24/04/2018

LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS

Reference number	Substance identification			
	Chemical name / INN	CAS Number	EC Number	Update Date
1	N-(5-Chlorobenzoxazol-2-yl)acetamide	35783-57-4	-	17/10/2010
2	(2-Acetoxyethyl)trimethylammonium hydroxide (Acetylcholine) and its salts	51-84-3	200-128-9	17/10/2010
3	Deanol aceglumate (INN)	3342-61-8	222-085-5	15/10/2010
4	Spironolactone (INN)	52-01-7	200-133-6	15/10/2010
5	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid (Tiratricol (INN)) and its salts	51-24-1	200-086-1	17/10/2010
6	Methotrexate (INN)	59-05-2	200-413-8	15/10/2010
7	Aminocaproic acid (INN) and its salts	60-32-2	200-469-3	17/10/2010
8	Cinchophen (INN), its salts, derivatives and salts of these derivatives	132-60-5 / 5949-18-8	205-067-1 / 227-710-5	17/10/2010
9	Thyropropic acid (INN) and its salts	51-26-3	-	17/10/2010
10	Trichloroacetic acid	76-03-9	200-927-2	15/10/2010
11	Aconitum napellus L. (leaves, roots and galenical preparations)	84603-50-9	283-252-6	15/10/2010
12	Aconitine (principal alkaloid of Aconitum napellus L.) and its salts	302-27-2	206-121-7	15/10/2010
13	Adonis vernalis L. and its preparations	84649-73-0	283-458-6	15/10/2010
14	Epinephrine (INN)	51-43-4	200-098-7	15/10/2010
15	Rauwolfia serpentia L., alkaloids and their salts	90106-13-1	290-234-1	17/10/2010
16	Alkyne alcohols, their esters, ethers and salts	-	-	17/10/2010

Ingredient management

Restricted substances

- **Annex III** of the EU Cosmetics Regulation provides the List of substances which cosmetic products **must not contain except subject to the restrictions** laid down (negative list).
- The list contains the **substance identification** (Chemical name/INN, INCI name, CAS Number and EC number) and the **restrictions of use with the maximum concentration** in ready for use preparation of each restricted substance.

File creation date: 09/04/2019

Annex III, Last update: 24/10/2018

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

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings	Update date
	Chemical name / INN	Name of Common Ingredients Glossary	CAS Number	EC Number	Product Type, body parts	Maximum concentration in ready for use preparation	Other		
1a	Boric acid, borates and tetraborates with the exception of substance no 1184 in Annex II	BORIC ACID	10043-35-3	233-139-2	(a) Talc (b) Oral products (c) Other products (excluding bath products and hair waving products)	(a) 5% (as boric acid) (b) 0.1% (as boric acid) (c) 3% (as boric acid)	(a) Not to be used in products for children under 3 years of age Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (as boric acid) (b) Not to be used in products for children under 3 years of age	(a) Not to be used for children under 3 years of age Not to be used on peeling or irritated skin (b) Not to be swallowed Not to be used for children under 3 years of age (c) Not to be used for children under 3 years of age	24/11/2016

Ingredient management

Positive lists

- The Cosmetics Regulation lays down **positive lists** of the only substances that can be used for three categories of ingredients.

Colorants

- Annex IV of the Cosmetics Regulation lays down the list of **colourants** allowed in cosmetic products in the EU.

Preservatives

- Annex V of the Cosmetics Regulation lays down the list of **preservatives** allowed in cosmetic products in the EU.

UV-filters

- Annex VI of the Cosmetics Regulation lays down the list of **UV-filters** allowed in cosmetic products in the EU.

Ingredient management

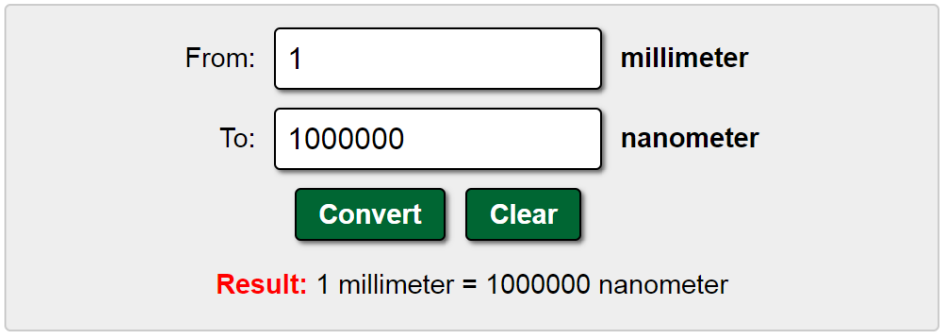
CMR substances

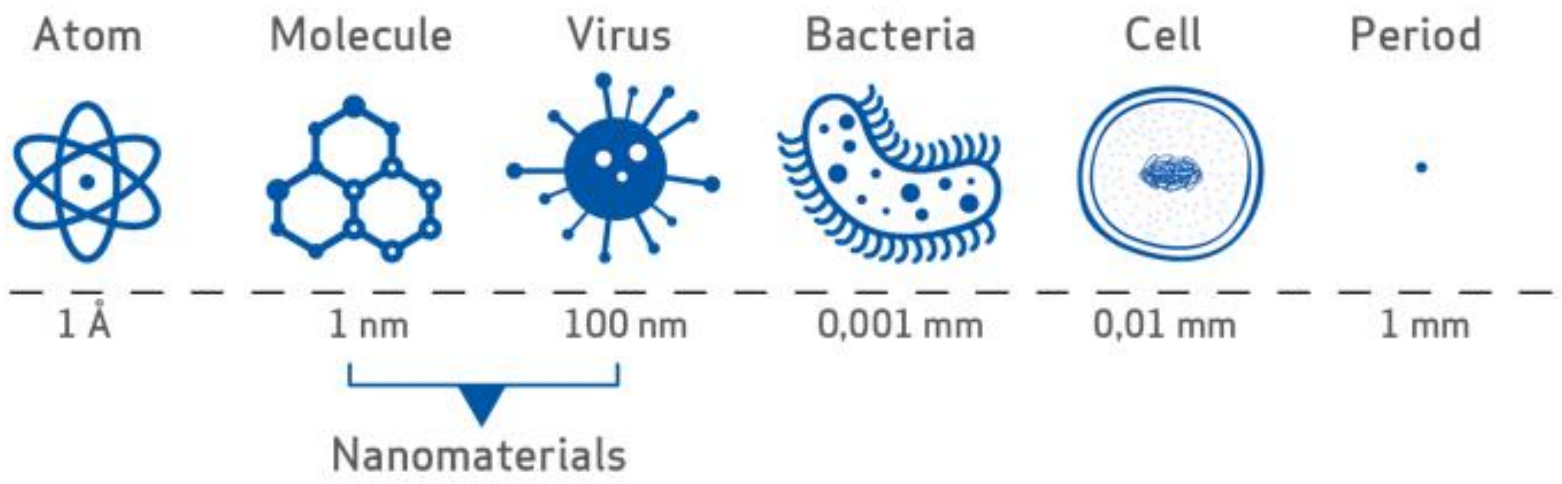
- As a general principle, substances classified as **carcinogenic**, **mutagenic**, or **toxic for reproduction** (CMR substances) are banned for use in cosmetic products.
- **Exceptions** to this general rule are possible where the substance has been **evaluated by the SCCS** and found safe for use in cosmetic products taking account of **the exposure from all sources** (cosmetics, chemicals, food, medicinal products) according to a comprehensive approach.

Ingredient management

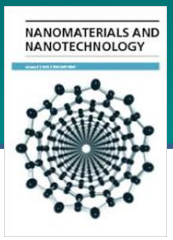
Nanomaterials

- "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**."





Ingredient management

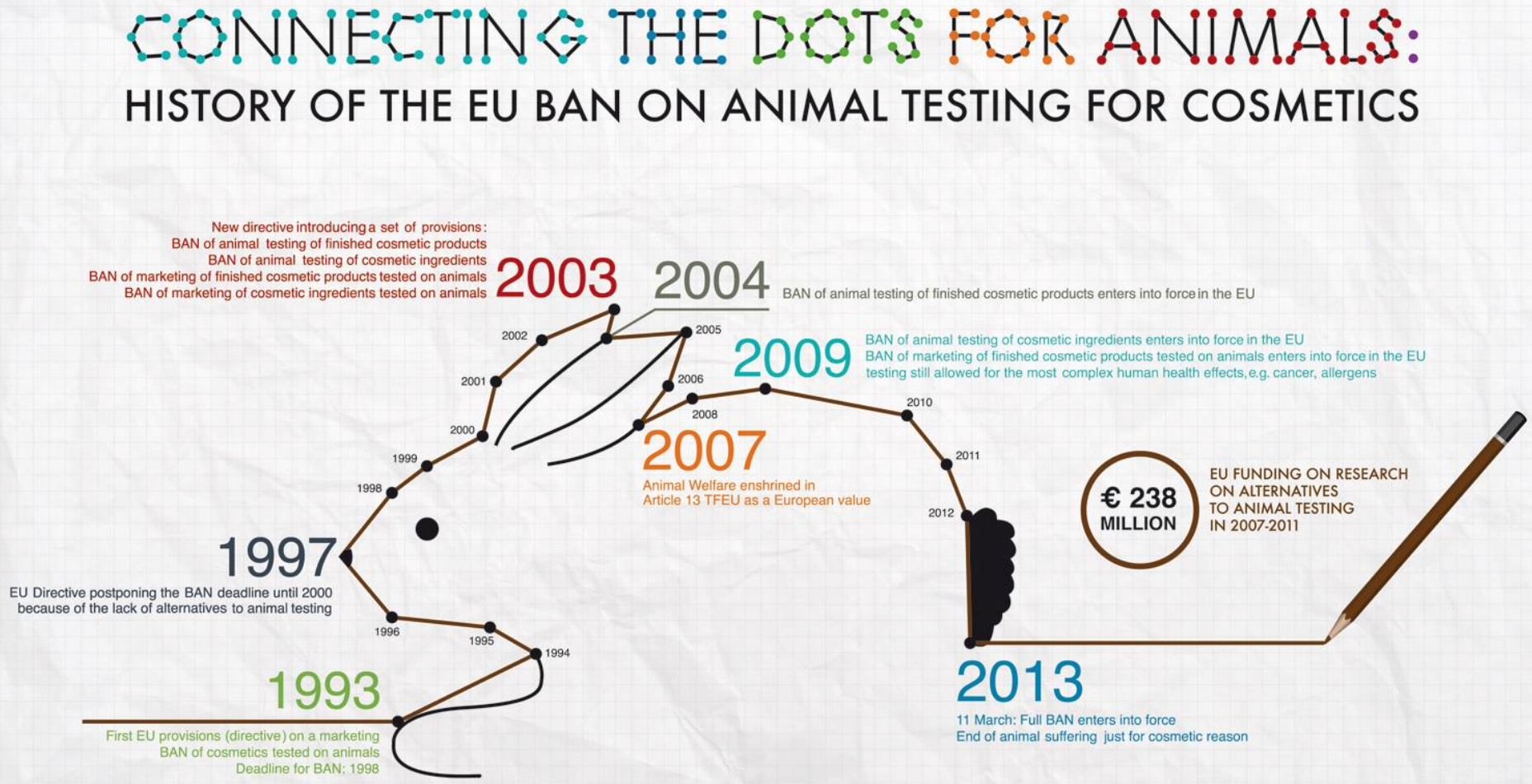


Nanomaterials

- Amongst the substances subject to the positive lists, 4 nanomaterials have been authorized:
  - **3 UV-filters**: titanium dioxide, zinc oxide and tris-biphenyl triazine;
  - **1 colourant**: carbon black (nano).
- Products containing nanomaterials must be **notified six months** prior to placing on the market with full safety information.
- In case of safety concerns → Scientific Committee on Consumer Safety (SCCS) **review** & **possible regulation** of the nanomaterial.
- **Labelling**: in the list of ingredients, the name of the nanomaterial must be followed by the word 'nano' in brackets **[nano]**.

Ingredient management

Ban on Animal Testing



Ingredient management

Ban on Animal Testing

- Since March 2013 the Cosmetics Regulation prohibits:

TESTING BAN

- the performance of **animal testing**
- in **the EU**
- of **finished cosmetic products** and **ingredients**
- **in order to meet** the requirements of the Regulation

MARKETING BAN

- the **placing on the market** of cosmetic products
- where the **final formulation** or the **ingredients**
- were **tested on animals**
- **in order to meet the** requirements

Ingredient management

Ban on Animal Testing

- Animal data **generated before the deadlines (2009/2013)** can continue to be relied on in cosmetics safety assessment.
- Animal data **generated for multi-purpose ingredient** and for **compliance with other, non-cosmetics legal frameworks** (EU and non-EU) can be relied on in cosmetics safety assessment;
- Animal data **generated for substances that are exclusively used in cosmetics** cannot be relied on in cosmetics safety assessment.

Ingredient management

Cosmetic Ingredients Database

- CosIng is the European Commission **database** for information on cosmetic substances and ingredients contained in the:
  - Cosmetics Regulation
  - Cosmetics Directive
  - Opinions of the Scientific Committee for Consumer Safety

Cosmetic Products Notification Portal (CPNP)

- **Before being placed on the European market**, all cosmetics products must be **listed** on a centralised database, the **Cosmetic Products Notification Portal (CPNP)**, managed by the European Commission.
- The CPNP is **accessible** to:
  - **Competent Authorities** (for the purposes of market surveillance, market analysis, evaluation and consumer information)
  - **European Poison Centres** (for the purposes of medical treatment)
  - Cosmetic products **responsible persons**
  - **Distributors** of cosmetic products.

Post-market controls

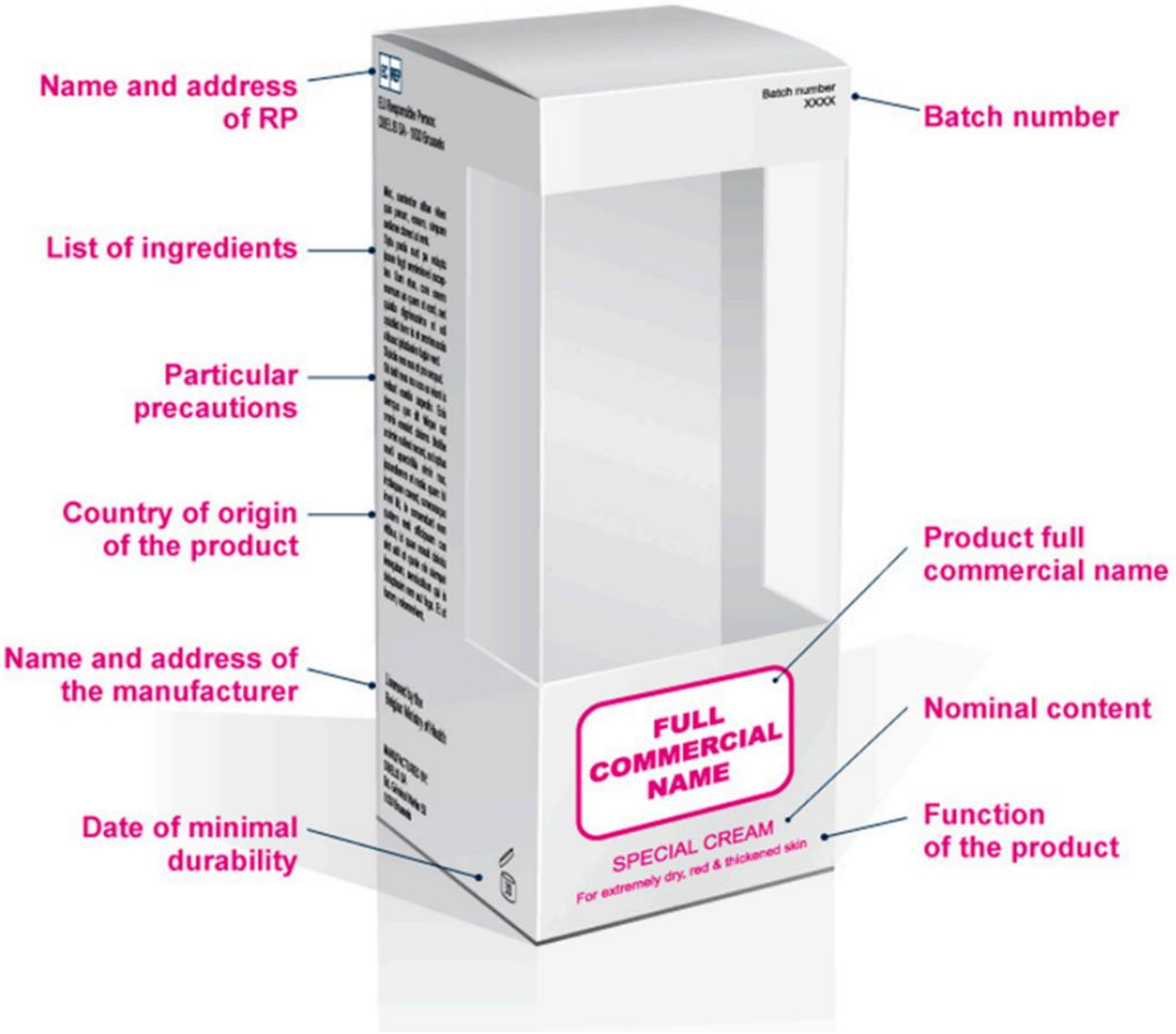
- EU **Member States are responsible** for the surveillance of their own markets for cosmetics.
- In order to ensure a **coherent approach** to consumer products issues, the market surveillance authorities of all EU countries established the **Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC)**.
- Member States **monitor compliance** via in-market controls of the cosmetic products made available on the market.
  - Checks on cosmetic products and on the economic operators.
  - Checks on the PIF.
  - Physical and laboratory checks.
  - Checks to monitor compliance with GMP.

Cosmetovigilance

- Member States have to cooperate and exchange information on **serious undesirable effects** attributable to cosmetics use.

- The Cosmetic Regulation mandates:
  - the notification of SUEs to national authorities where the effect in question occurred;
  - the notification of any corrective measures taken by the Responsible Person or the distributor.
- The data on SUEs forms part of the **Cosmetics Product Safety Report (CPSR)**.

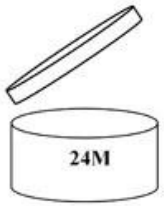
Labelling


Name and address of RP
List of ingredients
Particular precautions
Country of origin of the product
Name and address of the manufacturer
Date of minimal durability
Batch number
XXXX
Batch number
Product full commercial name
Nominal content
Function of the product
FULL COMMERCIAL NAME
SPECIAL CREAM
For extremely dry, red & thickened skin

Claims

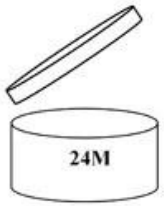
- Product claims and advertising are essential tools for informing consumers about characteristics and qualities and help them choose the products that best suit their needs and expectations.
- Today, virtually every cosmetic product placed on the EU market bears a type of communication which falls into the scope of product claims.
- For cosmetic product claims to meet their purposes adequately, it is important to have an efficient framework in place which ensures that they are fair and do not mislead consumers, taking into account the context and the marketing tools (irrespective of whether it is printed material, a TV advertisement or using any kind of new media such as internet or smart phones) in which such claims are shown.
- To achieve this, competent authorities in charge of market surveillance must be able to easily verify all claims based on

Labelling



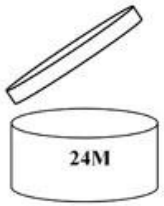
Labelling

Hour-glass:
It illustrates the Date of Minimum Durability (DOMD) when equal or below 30 months. The DOMD is defined by the stability test. The actual date must follow the symbol.



Labelling

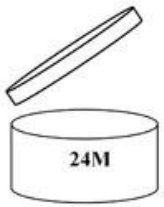
Hour-glass:
It illustrates the Date of Minimum Durability (DOMD) when equal or below 30 months. The DOMD is defined by the stability test. The actual date must follow the symbol.



Open-jar:
If the DOMD exceeds 30 months, the open-jar symbol will indicate the period after opening (PAO) defined by the combination of the stability test and challenge test.

Labelling

Hour-glass:
It illustrates the Date of Minimum Durability (DOMD) when equal or below 30 months. The DOMD is defined by the stability test. The actual date must follow the symbol.



Open-jar:
If the DOMD exceeds 30 months, the open-jar symbol will indicate the period after opening (PAO) defined by the combination of the stability test and challenge test.

Hand-in-book:
The hand-in-book symbol will indicate to the consumer that a card, tag or leaflet is enclosed with the product with more regulatory information.

Collegio Europeo di Parma

Seminar on: "EU Cosmetics Policy" 2019

Thursday 11 April 2019

Location: Collegio Europeo di Parma, Via Università 12, Parma	
11:00 - 12:30	***EU Cosmetics Law and Policy*** Prof. Patrick Deboyser
Location: Davines Headquarter, Via Ravasini 9/A, Parma	
14:00 - 14:45	**Presentation of Davines** Davide Bollati, Owner & Chairman
14:45 - 15:15	*Coffee break*
15:15 - 16:00	**Visit of Davines Headquarter**