NANOMATERIAL REGULATORY FRAMEWORK IN COSMETICS INDUCTRY – WHERE WE ARE & WHERE WE GO

Georgios Georgadakis
The Hellenic Cosmetic ,Toiletry & Perfumery Association -

Material documentation support by
Florian Schellauf / Cosmetics Europe

WHAT IS HAZARD? WHAT IS RISK?

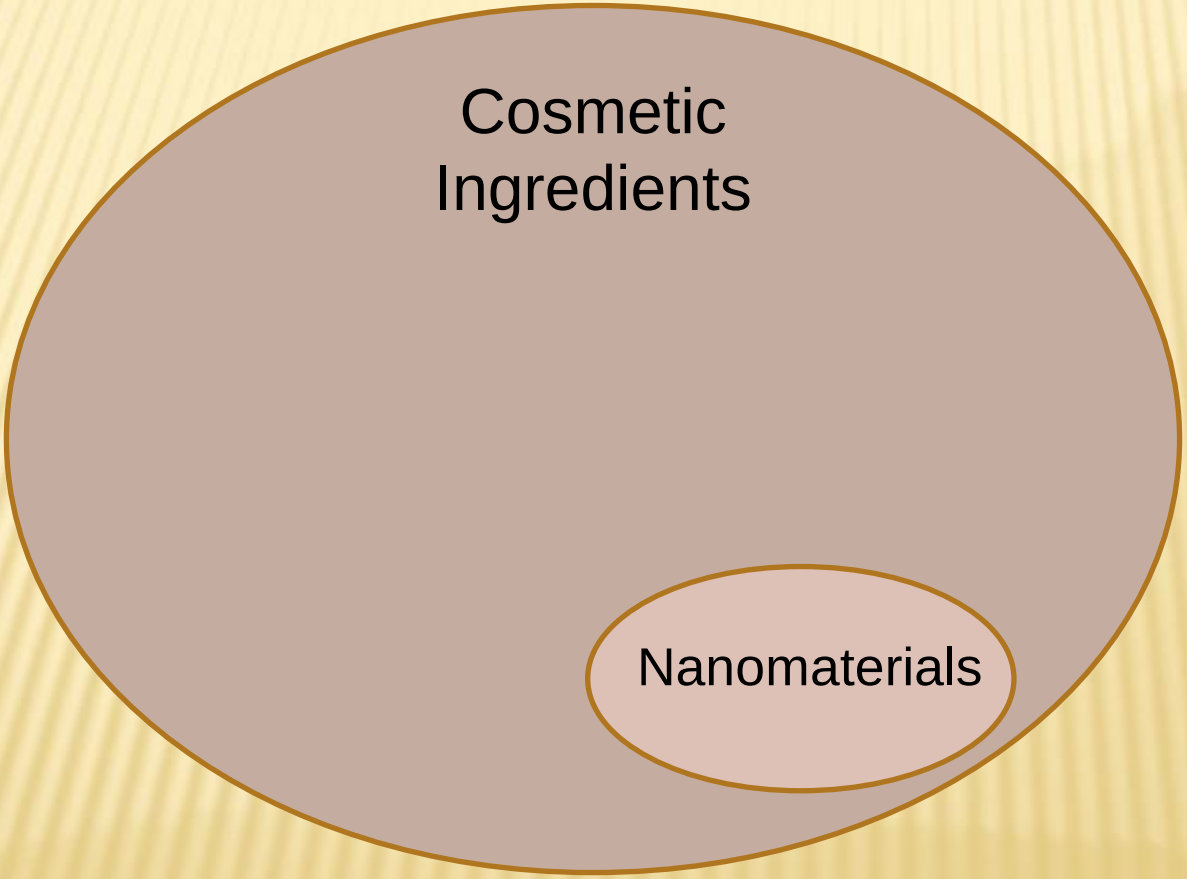
- Very often these two terms are confused
- Hazard is the intrinsic property of a chemical, item, tool etc. to theoretically cause harm.
- Risk is the probability that the exposure to the hazard actually causes harm.
- Assessment of risk involves many considerations in addition to the hazard, like use conditions, protective measures in place, route of exposure, duration of exposure.

IS « NANO » A HAZARD? PERCEPTION

Many stakeholders in the discussion around nanomaterials perceive « nano » as a negative property inherent in a material

For instance the Erosion, Technology and Concentration (ETC) competition for a nano hazard label used the following graphic:

DEFINITION OF A NANOMATERIAL – WHAT IS ITS PURPOSE?



THE COSMETICS REGULATION AND NANOMATERIALS – DEFINITION -1

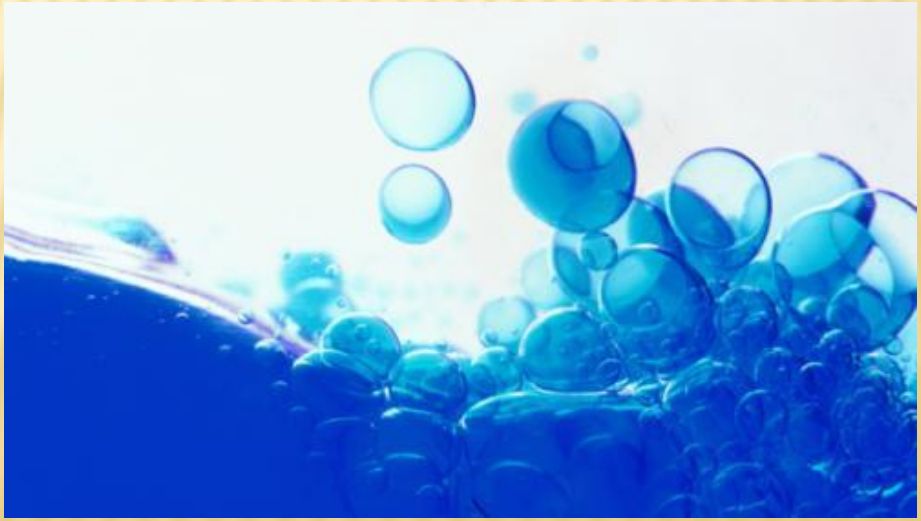
The definition of a nanomaterial in the Cosmetics Regulation takes into account risk elements:

- *"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 100nm* " (Article 2(k))
- The legal requirements for nanomaterials under the CPR are linked to this definition.

THE COSMETICS REGULATION AND NANOMATERIALS – DEFINITION -2

An example of a risk-related element in the nano definition:

Stability and insolubility: some materials (vesicles/liposomes) in the nano size range exist in the product formulation, but dissolve upon contact with skin. Exposure of the consumer to these nanomaterials does not occur, and they are excluded from the scope of the definition.



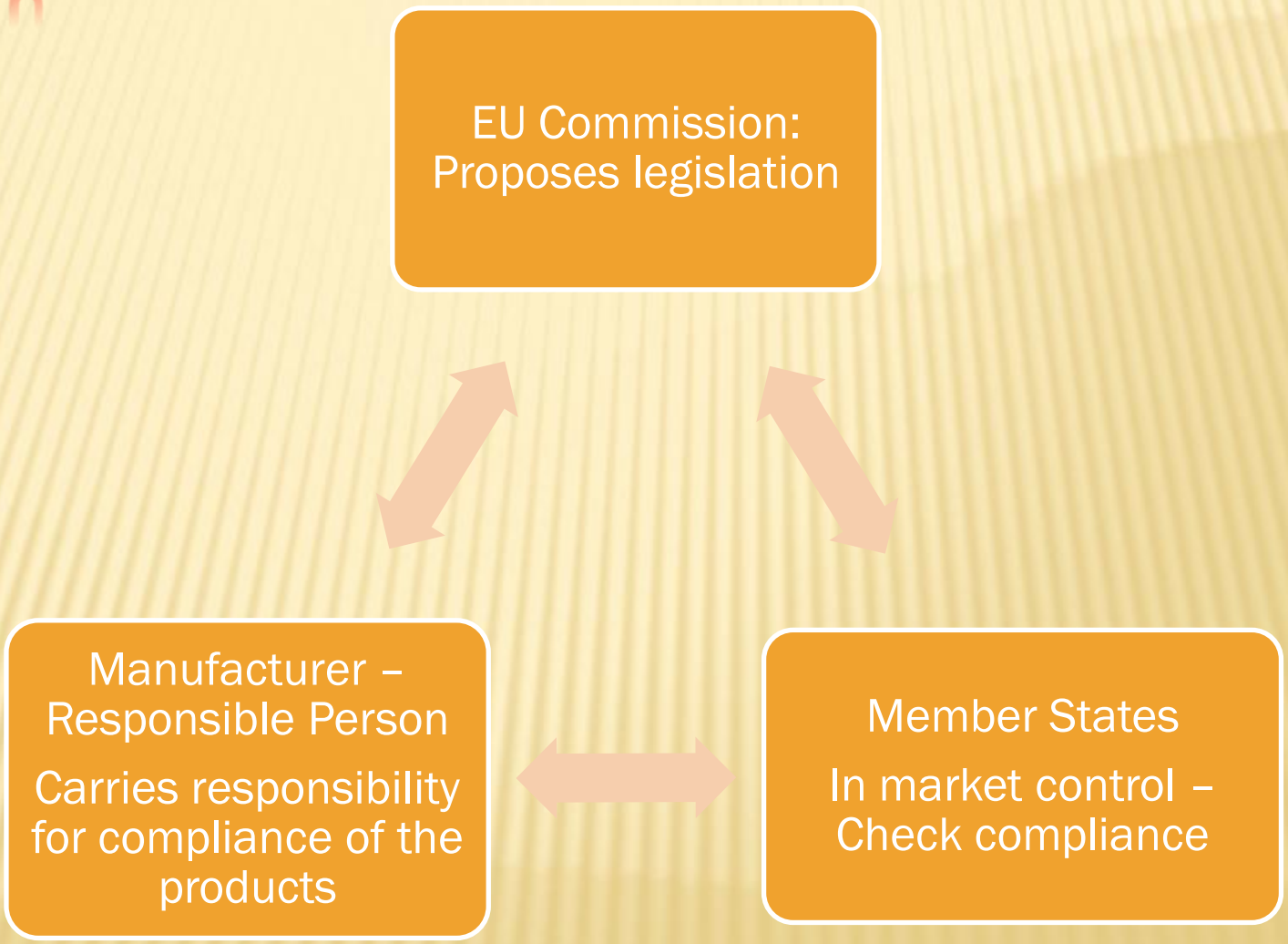
THE COSMETICS REGULATION AND NANOMATERIALS – DEFINITION - 3

- It is important to note that the definition in the Cosmetics Regulation is of a regulatory nature and needs to provide clear guidance to the regulated sector « what is in » and « what is out » of the scope of the requirements

THE COMMISSION RECOMMENDATION ON THE DEFINITION OF A NANOMATERIAL

- In October 2011 the Commission published a recommendation on the definition of a nanomaterial
- This definition for regulatory purposes is very broad and decribes any type of nanomaterial. It allows for a narrowing of the scope for specific sectors.

THE REGULATORY TRIANGLE FOR COSMETICS IN THE EU



PRINCIPLE OF SUBSTANCE REGULATION

- Arises from principle of “Responsible Person” and authorities’ in-market control
- The choice of safe ingredients is in the responsibility of the responsible person (and his safety assessor).
- For some classes of substances, however, the legislator has identified/maintained the need to introduce EU-harmonised restrictions → Annexes of the Regulation

Ingredients with specific attention

Colorants, Preservatives, UV-filters → positive list (Annex IV-VI) “Positive list materials”

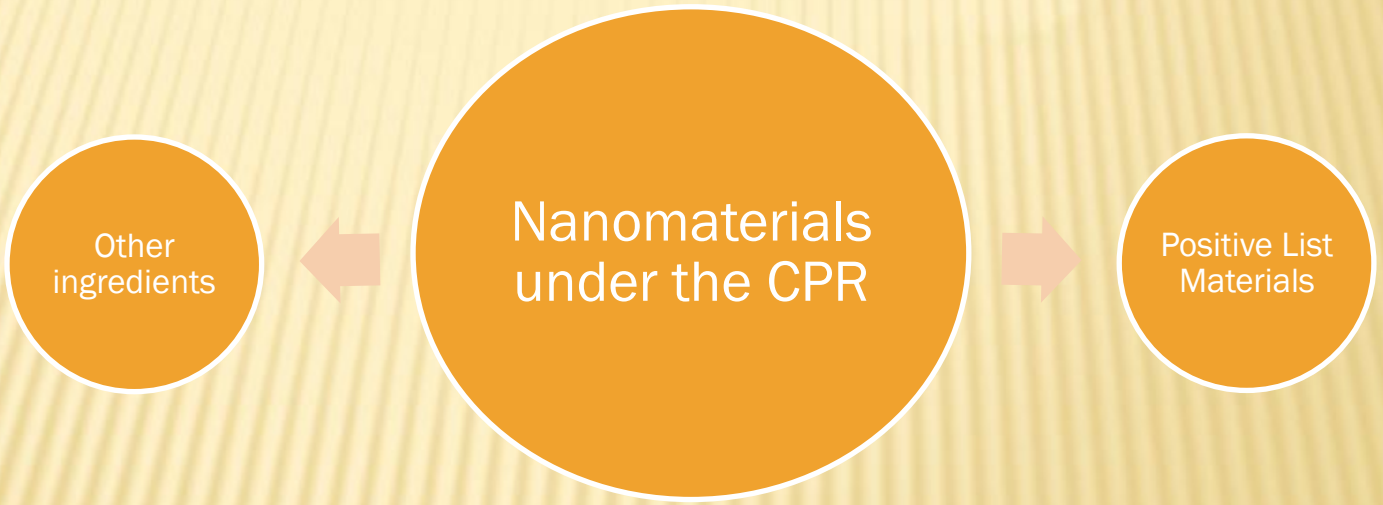
Specific substances of concern : banned / restricted → (Annex II - III)

CMR Substances : ban with exceptional derogations

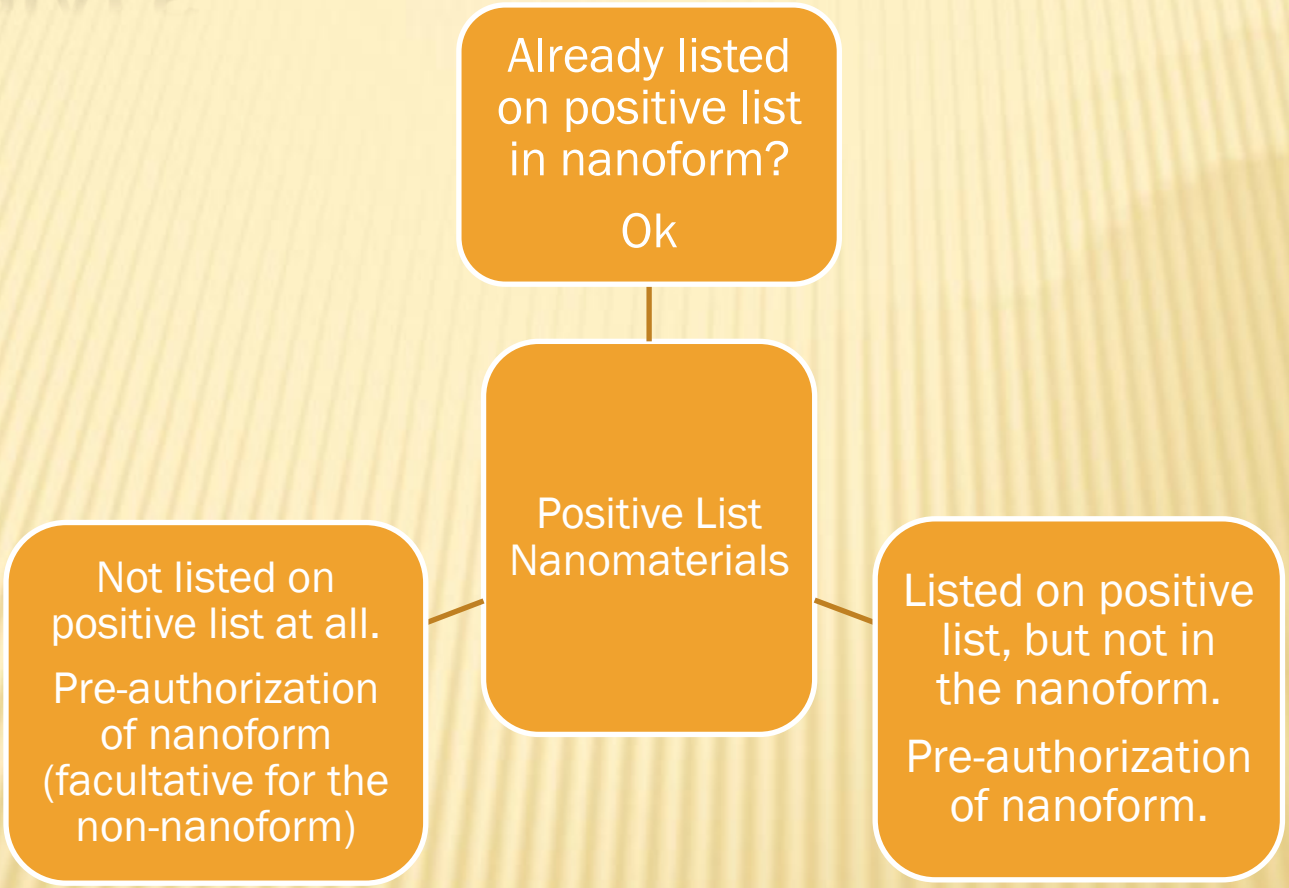
COSMETICS REGULATION - NANOMATERIALS

- Overview:
- ✓ Definition of a nanomaterial (Article 2(1)k)
- Notification Article 13: indication of presence of nanomaterials
- ➢ Notification Article 16
- Reporting requirements for the Commission
- Regular review of nano-related requirements (Article 16(11))
- ➢ Nano labelling

NANOMATERIALS – HOW DOES THE CPR APPROACH THEM?

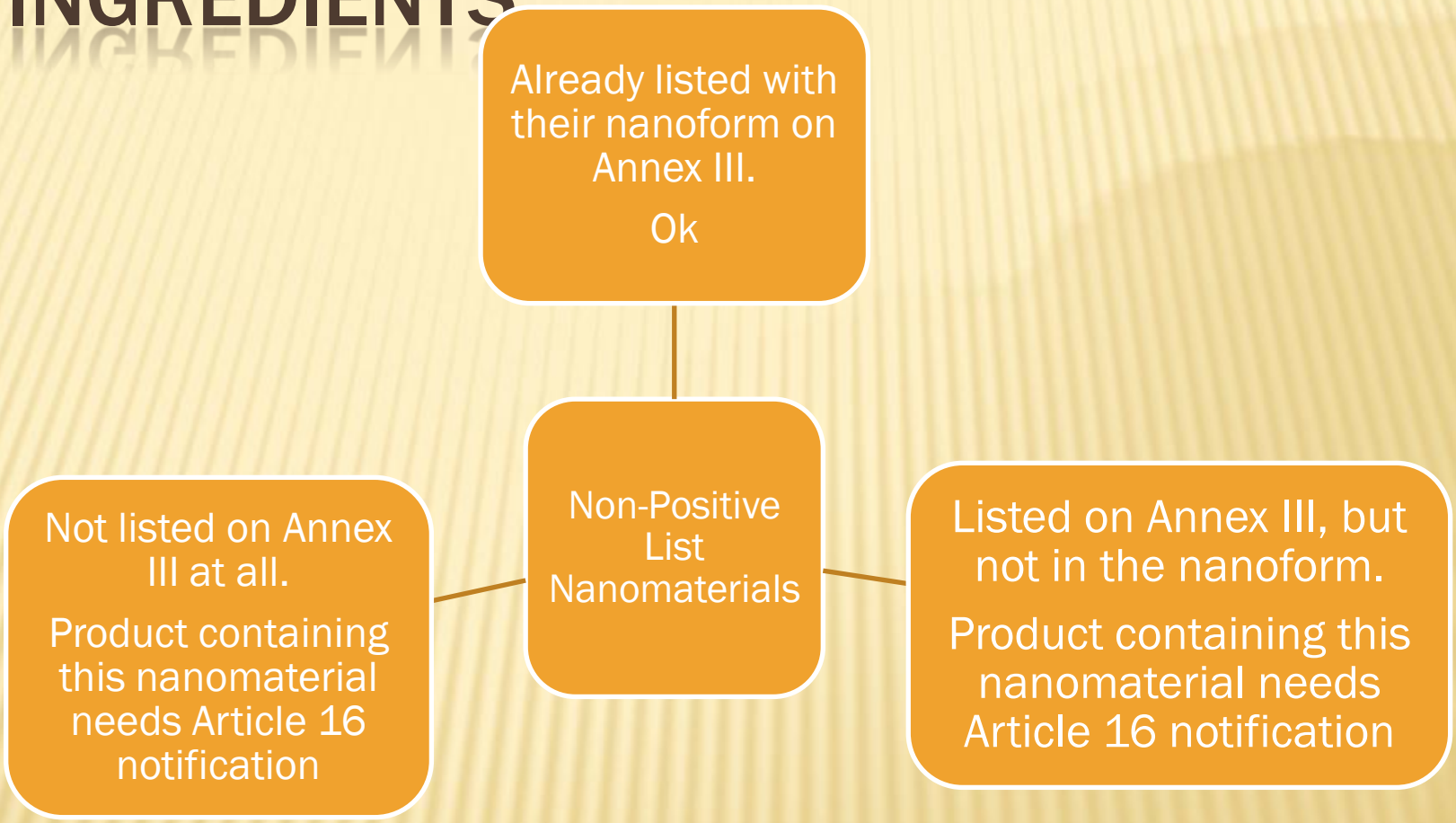


NANOMATERIALS – POSITIVE LIST MATERIALS



Pre-authorization for nanomaterials is the same standard process as for any other positive list materials.

NANOMATERIALS – NON-POSITIVE LIST INGREDIENTS



NB: Pre-authorization and Article 16 notification are mutually exclusive.

Nanomaterials in the Cosmetics Regulation - Article 16 Notification

A notification portal has gone live on 10 January 2013.

What information needs to be notified?

Substance identification
Specifications
Use information/Tonnage information
Toxicology profile/data
Safety assessment
Exposure assessment

Nanomaterials in the Cosmetics Regulation - Article 16 Notification - Process

Product Notification → Ingredient Assessment

Products notified under Art 16 can be marketed six months after notification, even if there is no SCCS evaluation or an ongoing evaluation.

THE COSMETICS REGULATION AND NANOMATERIALS – NANOLABELLING

Identification of nanomaterials in the ingredient list

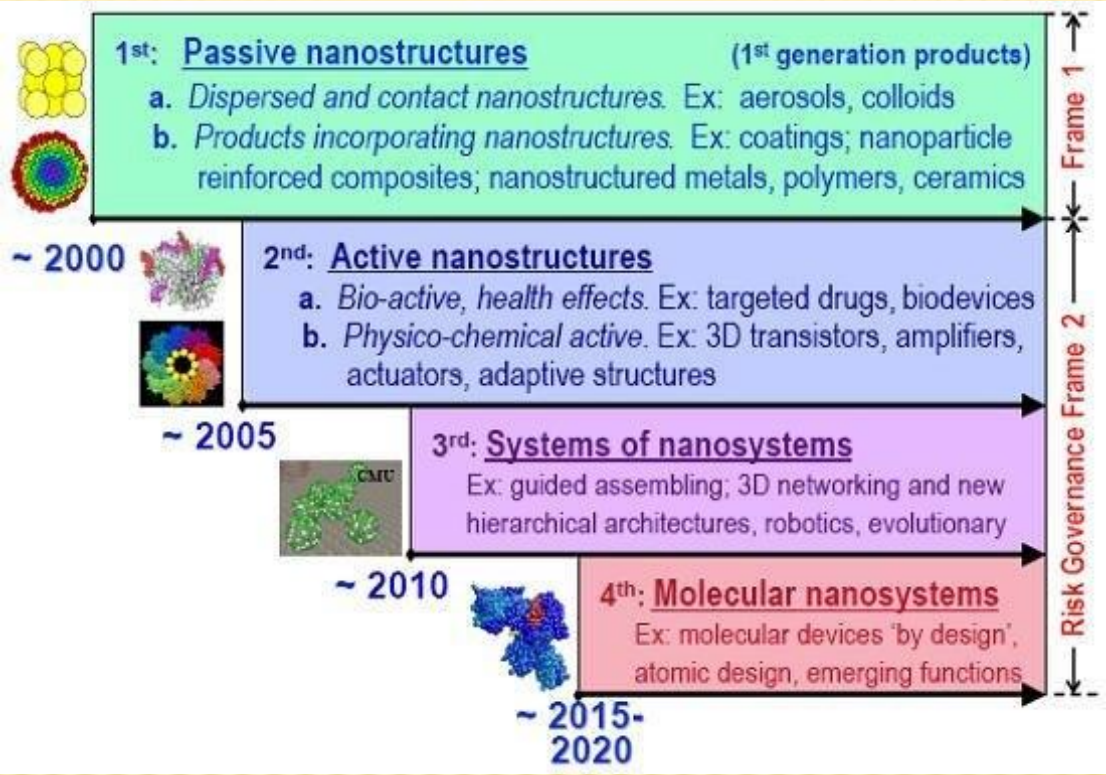
"The names of such ingredients shall be followed by the word nano in brackets"

= consumer information

≠ safety information, warning or hazard labelling

IMPLEMENTATION PROCESS OF NANOMATERIALS REGULATION IN THE COSMETICS INDUSTRY

WHAT ARE WE TALKING ABOUT…



Nanomaterials were developed in stages. Only a limited number of first generation materials is used in cosmetics.

THE RECAST OF THE COSMETICS DIRECTIVE

- Cosmetics are acting as regulatory spearhead sector
- Cosmetics Regulation was passed in 2009 at the height of the EU debate on nanomaterials – a time of questions rather than answers
- All stakeholders realise that practical implementation was going to be very difficult

COSMETICS REGULATION : IMPLEMENTATION

- Notification of products containing nanomaterials started in January 2013.
- Products containing nanomaterials needed to comply with the labelling requirements after 11 July 2013.
- Industry had to start preparing itself for compliance more than two years before these dates.
- However, cosmetic companies achieved compliance based on experience gained and best practices.

DEFINITION-1

- Nanomaterials in Cosmetics were regulated in detail long before the EU started work on a consistent framework for nanomaterials
- Neither the cosmetic-specific definition, nor the overarching Commission Recommendation are self explanatory.
- They need interpretation and guidance for practical implementation

DEFINITION-2

- No official guidance has been developed on how to interpret the cosmetic nano-definition and how it relates to the overarching Commission Recommendation.
- Control authorities entered the stage of in-market control, while cosmetic companies had two years of implementation work already behind them.
- Today, cosmetic companies and control authorities have increasingly the same understanding on how to work with the definition.

ANALYTICAL METHODS

- N.B.: The principle feasibility of a measurement with cutting edge equipment needs to be differentiated from routine methods and protocols accessible for every company (especially SMEs)
- No harmonized, routinely available analytical methods for the sample preparation, detection, characterization and quantification of nanomaterials in finished cosmetic products exist today.
- EU Commission sponsors important large-scale projects (Commission sponsored FP 7 projects) to avoid that different methodologies used to characterize nanomaterials lead to results, which cannot be directly compared.
- Recommended reading: Three JRC reports describing the state of the art.
- http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

Product nano notification:

The purpose of the system is defined upfront:

☑Information gathering

X Surveillance/traceability tool

☑Safety assessment

Product nano notification: learnings-1

One centralised system ensures a harmonised approach across the EU.

Avoid duplication: Use or integrate already existing structures. Take into account sectors that have systems already in place.

Harmonise and align definitions used, including the possibility to focus the scope of the definition for certain sectors (see Commission Recommendation).

Product nano notification: learnings-2

- Divergent requirements

→ No benefit for consumer safety

→ Increased administrative burden

→ Results which may not be comparable

In the light of divergent Member States initiatives the Article 16 nano notification process has always been presented as a system that “got it right”.

NANOLABELLING – HOW DID CONSUMERS REACT?

- Nanolabelling is now implemented in the cosmetic industry since July 2013.
- No changed behaviour by consumers has been observed by industry. Consumers still request efficient products with quality, independent whether they contain nanomaterials or not. Few consumers contact companies or associations for information.
- Surprisingly little attempts at “nano free” claims.
- Feedback and validation from consumer organisations could be helpful for debates

FUTURE EXPECTATIONS -1

- Nano catalogue 31.12.2016
  - Remains a work in progress

- Regulating the SCCS Opinions on specific substances.
  - TiO2 : Reg 2016_1143 (color , UV)
  - ZnO : Reg 2016_621 (UV)
  - Carbon Black Reg 2016_1120 (color)
  - ETH-50 Reg 2014_866 (UV , preservative)

FUTURE EXPECTATIONS -2

- What about Innovation in Cosmetics based on nanomaterials ? Limited results expected due to :
  - NGOs pressure to stop using nanos
  - Strict regulation of the use of nanomaterials
  - The definition of cosmetics does not allow much to expand the functional categories of nanos (UV filter , coloring , preserving).