Product Stewardship - Cosmetics (updated)

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REGWATCH NETWORK - COSMETIC NW

We are expecting you to join the RegWatch Cosmetic NW.

If you have any questions, please feel free to contact NW at any time.

WANNA JOIN? - Contact Sunmin.PARK

COSMETIC NW Google Group HERE

COSMETIC NW SPACE to share HERE (Contact Pauline De La Cruz)

COSMETIC NW Recent W/W meeting minutes HERE (Contact Pauline De La Cruz)

COSMETIC NW Shared Drive

How to use IT tool for Cosmetic?

- 3E Insight & News
    - Regulatory texts and Expert Summary
    - Regulatory database (CAS No. List)
    - Sub-set regulatory Scopes / MyProduct Regulatory amendment notifications

EU INTRODUCTION

Cosmetic products placed on the EU market must be safe. The manufacturer is responsible for the safety of their products, and must ensure that they undergo an expert scientific safety assessment before they are sold. A special database with information on cosmetic substances and ingredients, called **CosIng** , enables easy access to data on these substances, including legal requirements and restrictions.

BORDERLINES

A **product** that restores, corrects, or modifies physiological functions by exerting a pharmacological, immunological or metabolic action, shall be qualified as a medicinal product. However, products that, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions, may be qualified as cosmetic products. The **qualification of a product** is to be decided by the national competent authorities, under the supervision of the courts, on a case-by-case basis, taking into account all the characteristics of the product. In addition, the use of any ingredient in cosmetic products must be supported by a safety assessment of the product.

Definition

Any **substance or mixture** i ntended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

EU LEGISLATION

Regulation (EC) N° 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. It provides a robust, internationally recognized regime, which reinforces product safety while taking into consideration the latest technological developments, including the possible use of nanomaterials and meeting the ban of animal testing.

Manufacturers need to follow specific requirements in the preparation of a product safety report prior to placing a product on the market.

Only cosmetic products for which a legal or natural person is designated within the EU as a 'responsible person', can be placed on the market.

Manufacturers will need to notify their products only once via the EU cosmetic products notification portal (CPNP).

A responsible person will have an obligation to notify serious undesirable effects to national authorities and they will be also obliged to share the information with other EU countries.

Colorants, preservatives and UV-filters, including those that are nanomaterials must be explicitly authorized. Products containing other nanomaterials not otherwise restricted by the cosmetics regulation will be the object of a full safety assessment at EU level if the Commission has concerns. Nanomaterials must be labelled in the list of ingredients with the word 'nano' in brackets following the name of the substance, e.g. 'titanium dioxide (nano)'.

EU DOSSIER PREPARATION FOR COSMETIC PRODUCTS

The **Cosmetic Regulation** requires the constitution of the Product Information File including the Cosmetic Product Safety Report (in English language) and a notification on the CPNP.

1. Preparation of ***Cosmetic Product Safety Reports (CPSR)*** , with a review of toxicological properties of ingredients and impurities.
2. ***Constitution of Product Information File (PIF)*** including a description of the cosmetic product, the ***CPSR*** , a description of the manufacturing process and a statement of compliance with good manufacturing practice (GMP), the proof of the effect claimed for the cosmetic product, the data relating to the development of the safety assessment of the cosmetic product and its ingredients.
3. Notification of the cosmetic product on the CPNP (notification Portal).

COSMETIC PRODUCT NOTIFICATION PORTAL (CPNP)

It is a **free of charge online notification system** . When a product has been notified in the CPNP, there is no need for any further notification at national level within the EU.

The CPNP is making this information available electronically to Competent Authorities, Poison Centers established by the Member States.

EU COSING

It is the **EU COMMISSION** database for information on ingredients & substances where CAS, ELINCS or EINECS numbers can be searched for.

Ingredient assigned with an INCI name that appears in the inventory section of **CosIng** does not mean it is to be used in cosmetic products nor approved for such use.

Concerning ingredients used in cosmetic products as colorants, preservatives and UV filters, only those authorized in Annexes IV, V, VI respectively to Cosmetic Regulation No 1223/2009 are listed in **CosIng. CosIng** may also list ingredients known to be used in medicinal products.

EU COSMETIC PRODUCTS CONTAINING NANOMATERIALS

The CPNP also contains a separate module for cosmetic products containing nanomaterials. This notification has to be done 6 months prior to the placing on the market of the cosmetic product. If the European Commission has concerns regarding the safety of a nanomaterial, it may request the scientific committee on consumer safety to perform a risk assessment.

In cosmetic products, reference to 'nanotechnology' usually means the use of insoluble nanoparticles as ingredients.

EU COSMETIC PRODUCTS CONTAINING CMRs

Cosmetics legislation also contains provisions on using carcinogenic, mutagenic, or toxic for reproduction substances (**CMR substances**) in cosmetic products. In general, the use of CMR substances is prohibited, except for in exceptional cases.

EU ENDOCRINE DISRUPTORS

Endocrine Disruptors (ED) are chemicals that may interfere with the hormonal system and, as a result of that, produce harmful effects in both humans and wildlife.

The regulation includes a system of restrictions on and bans of certain substances in cosmetics. Restrictions are based on the scientific committee on consumer safety's (SCCS) risk assessments. These assessments address scientific concerns about the endocrine-disrupting properties of substances in cosmetics as well as other substances of concern.

>> Refer to Endocrine Disruptors page .

EU BAN ON ANIMAL TESTING

The legislation on cosmetic products defined a regulatory framework for the phasing out of animal testing for cosmetic purposes. Specifically, it established :

- a testing ban / prohibition to test finished cosmetic products and cosmetic ingredients on animals;
- a marketing ban / prohibition to market finished cosmetic products and ingredients in the EU which were tested on animals.
    - The testing ban on finished cosmetic products applies since *11 September 2004* .
    - The testing ban on ingredients or combination of ingredients applies since *11 March 2009.*
    - The marketing ban applies since *11 March 2009* for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity, and toxicokinetics.
    - For these specific health effects, the marketing ban applies since *11 March 2013* , irrespective of the availability of alternative non-animal tests.

EU MICROPLASTICS

ECHA – REACH ANNEX XV RESTRICTION REPORT (PROPOSAL FOR A RESTRICTION)

The ECHA proposal for **Cosmetics** is currently the following:

- Ban on microbeads as soon as Restriction comes into effect (EIF).
- Ban for microplastics in Rinse Off cosmetics products with 4 year transition period (Enter into Force date + 4 years).
- Ban for microplastics in Leave On cosmetics products with 6 years transition period (Enter into Force date + 6 years).
- The future legislation is expected by the end of 2020 (third quarter?).

>> Information provided from the official website from the European Union .

Contact

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