

## Regulation of cosmetic ingredients

# Current Highlights and Upcoming Deadlines

In a context of intense political pressure, it is essential for companies to anticipate the accelerating pace of regulatory change. To achieve this, Cosmed has identified a number of key steps that regulatory departments need to take in order to prepare their company's cosmetics business as effectively as possible.

### Nanomaterials: the work continues...

Following the European Commission's recommendation n° 2022/C229/01 on the new definition of "nanomaterial", published in June 2022, discussions on the subject intensified in 2023, leading to various publications by the main national and European players (SCL, Centre NanoMesureFrance, JRC, ANSES, DGC-CRF), and work will continue in 2024. 2 major events are expected:

- ▶ The forthcoming publication of the 1<sup>st</sup> Omnibus "Nano". This was prompted by the European Commission's observation that most of the SCCS opinions on the subject were inconclusive due to a lack of data, and the desire to set up an omnibus regulatory process. This first "nano" omnibus provides for the addition of 5 "nano" entries to the annex of prohibited substances of the Cosmetics Regulation and one entry to the annex of restricted substances (specifically nano hydroxyapatite, following the favourable opinion SCCS/1648/22).
- ▶ The publications of the NanoMesureFrance center (guide and questionnaire), which will be an invaluable aid to companies by providing a methodology for the characterisation of substances.

### Use of the CBD: Europe gets involved

Discussions on the use of cannabidiol (CBD) in cosmetics are underway in the European Commission's Cosmetics Working Group, in which Cosmed participates. Opinions remain very divided

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among Member States, as interpretations and sensitivities vary from one country to another regarding this "borderline" substance. As the plant is currently not regulated in cosmetics, this booming market will soon come under strong regulatory pressure:

- ▶ On 1<sup>st</sup> June 2023, the European Commission launched a 15-month call for data – until 30<sup>th</sup> September 2024 – to assess the safety of its use in cosmetics. Approval will only be possible if its safety in use is demonstrated and the presence of traces of THC, the molecule responsible for the psychotropic effects of cannabis, is assessed.
- ▶ On 6<sup>th</sup> June 2023, the European Chemicals Agency (ECHA) published its intention to classify the substance as reprotoxic under the CLP Regulation. Anses initiated this harmonised classification process. The intention to classify should be ▶▶▶



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# REGULATION

▶▶▶ submitted for comment in 2024.

In the absence of data submitted by industry demonstrating the safety of its use, CBD could be banned for use in cosmetics.

## Microplastics: Banning rules now published

After much discussion, Regulation (EU) 2023/2025 on microplastics was published on 26<sup>th</sup> September 2023. The text is not part of the Cosmetics Regulation, but consists of an amendment to Annex XVII of the Reach restrictions. It aims to phase out synthetic polymers that meet the definition of microplastics and are intentionally added to all consumer products, including cosmetics.

Echa has defined microplastics as synthetic microparticles in solid form, consisting of polymers, less than 5 mm in size, insoluble and non-biodegradable. Although there are exemption criteria, the regulation introduces reporting and labelling requirements. The aim of the regulation is to monitor the use of microplastics throughout the supply chain up to consumer use in order to prevent them from entering the environment.

The ban will be phased in according to product category: four years for rinse-off products (October 2027), six years for non-rinse-off products (October 2029) and twelve years for make-up (October 2035). However, manufacturers need to start assessing now the presence of microplastics in these formulations and the possibilities for reformulation, especially as the deadlines for labelling (from 2025) and reporting (from 2026, depending on the actor) are much closer to the ban dates.

## The hunt for PFAS continues

The acronym stands for per- and poly-fluoroalkylated substances used for a variety of purposes: emulsifiers, antistatic agents, stabilisers, surfactants, film formers and viscosity enhancers. The European Commission's Cosing database lists no less than 170 of these substances in cosmetics. These

substances are controversial because of their harmful effects on the environment and their potential effects on health. The European Chemical Strategy for Sustainability therefore plans to phase them out, starting with the subgroup PFHxA (undecafluorohexanoic acid). The draft regulation is expected to be adopted in 2024. It will not have a direct impact on the cosmetics sector, but manufacturers should remain vigilant as PFHxA may be present as an impurity and/or as a degradation product of intentionally added PFAS.

The European Federation for Cosmetic Ingredients (EFfCI) is currently assessing the potential impact of the expected presence of traces from manufacturing processes, water and the environment. To be continued...

## Salicylate esters under evaluation

In 2023, the European Commission closed its call for data on the use of salicylic esters and/or salicylates used in cosmetic products that are metabolised to salicylic acid. This call for data had two objectives: firstly to identify these esters and secondly to assess the safety of their exposure. This could potentially affect the use of many substances identified as ingredients of perfumes, but also of authorised preservatives and certain UV filters such as homosalate and ethylhexyl salicylate. It is too early to determine the future of these substances. A dossier will be submitted to the SCCS in 2024.

## Tea tree, a difficult defence...

At the end of 2022, a proposal for the harmonised classification of Tea Tree Oil (TTO) as a category 2 reprotoxic (suspected) raised concerns about its use in cosmetic products in accordance with Article 15 of the European Cosmetics Regulation. At the beginning of 2002, Cosmed took the initiative to set up a TTO Task Force, composed of French and European companies, with the aim of defending the use of TTO in cosmetics by preparing an SCCS dossier. However, at the last meeting of the Risk

Assessment Committee (RAC) at the end of November 2002, the experts decided to re-evaluate the classification of TTO and to classify it as a category 1B reprotoxic substance. The official opinion of the RAC on this new classification was published on the Echa website on 9<sup>th</sup> February 2024, starting the 6-month countdown for submission of the dossier to the SCCS.

This reclassification to category 1B further complicates the defence of its use in cosmetics. The TTO Task Force is actively working not only on the submission of a more robust SCCS dossier, taking into account the overall exposure and defending a specific use, but also on a dossier demonstrating that there is no alternative to TTO in cosmetics for the selected uses and a dossier ensuring food safety.

Despite the efforts currently being made to defend this substance, it is crucial to bear in mind that if this fails, the date for the ban of TTO in cosmetics would be around July 2026.

## Octocrylene, a UV filter under pressure !

Octocrylene is a UV filter whose safety for consumers has been confirmed by the SCCS in 2021 for use up to 9% in spray products and up to 10% in other products. However, it is now being criticised because of concerns about its impact on the environment. This UV filter does not meet the criteria defined by the Reach regulation for inclusion on the list of substances of very high concern (SVHC) and, subsequently, substances subject to authorisation, but it is the subject of an intention to restrict it, led by Anses, in view of its impact on the environment.

Sunscreen products are essential to protect consumers from the harmful effects of UV radiation.

Hazard assessment data are still lacking, as is the method for assessing environmental exposure, which needs to be refined. Cosmed reiterates the importance of relying on solid scientific data demonstrating an unacceptable risk

