

# BRIEFING

THE REGULATORY EXPERTS' NEWSLETTER IN THE COSMETICS INDUSTRY

4TH QUARTER 2024



# COSMED: Calendar of Major European Deadlines 2025

The entire Cosmed team wishes you a wonderful and prosperous year 2025!

To start the year 2025 on a high note, Cosmed has prepared a regulatory calendar to outline significant regulatory changes impacting the cosmetic industry.



- **Homosalate** [Regulation 2022/2195]: For products placed on the market from January 1, 2025, usage of this UV filter is restricted to face products (excluding sprays and aerosols) at a maximum concentration of 7.34%.
- With the application of Regulation 2024/996, new maximum concentration limits come into effect for placing products on the market:
  - · Triclocarban: Maximum 0.2%, prohibited in mouthwashes.
  - Triclosan: Maximum 0.3% in toothpastes (not for children under 3), hand soaps, body soaps/gels, nonspray deodorants, face powders, foundations, and nail cleaning products.



## Join us to discuss these updates and more!

- **2025 MARCH 26.27**
- PARIS AND STREAMING
- REGULATORY NEWS EUROPE - INTERNATIONAL

Infos & Registration







- Regulation 2024/996 set new restrictions for 5 substances:
- · Genistein: Maximum 0.007%.
- · Daidzein: Maximum 0.02%.
- · Kojic Acid: Maximum 1%, applicable only in face and hand products.
- · Arbutin: Maximum 7%, limited to face creams.
- · Alpha-Arbutin: Maximum 2% in face creams; maximum 0.5% in body lotions

Non-conpliant products cannot be placed on the market from February 1, 2025.

• **Nanomaterials** [Regulation 2024/858]: Products containing non-compliant or prohibited nano substances under the Omnibus nano (9 new banned substances and new restrictions on hydroxyapatite (nano)) cannot be placed on the European market.



• **4-Methylbenzylidene camphor** (4-MBC) [Regulation 2024/996]: currently allowed up to 4%, this UV filter are banned for products placed on the market.

Non-compliant products will have to be removed from the market by May 1, 2026.

 Non-compliant products with the new restrictions for Homosalate [Regulation 2022/2195, see January,1] must be removed from the market



• **Dimethyltolylamine and Trimethylbenzoyl Diphenylphosphine Oxide**: These substances used in nail varnish and artificial nails are banned under Omnibus VII. Products containing these substances must be removed from the market.



- **Microplastics** [Regulation 2023/2055]: New mandatory labeling "do not rinse before disposal/sorting" will apply to:
  - · Finished products under exemption 5b.
  - · Raw materials received at manufacturing sites, exempted under criterion 4a.

Non-compliant products must be removed from the market.



- Following the application of regulations earlier in 2025, non-compliant products must be removed from the market:
  - · New restrictions on Triclocarban and Triclosan (preservatives)
  - · New restrictions on Genistein, Daidzein, Kojic Acid, Arbutin, and alpha-Arbutin
  - · Ban on 9 nanomaterials
- Vitamin A (Retinol and derivatives) [Regulation 2024/996]: New maximum concentrations and labelling are set for products placed on the market:
  - · Maximum 0.05% in body lotions.
  - · Maximum 0.3% in other products.
  - · Labelling requirement: "Contains Vitamin A. Consider your daily intake before use."

Non-compliant products will have to be removed from the market by May 1, 2027.



• Application of anti-deforestation regulation (2023/1115)

While some deadlines extend beyond 2025, it is crucial to prepare for major changes, including the addition of new allergens to your INCI lists for 2026 and the ban on styrenes by 2030. Additional rules regarding microplastics will apply by 2027 for rinse-off products and by 2029 for leave-on products containing over 0.01% of microplastics.



## Export to Russia: Get Ready for QR Codes!



Initially applicable to perfumes, the implementation of a unique QR code for each product unit (serialization) now becomes mandatory for all cosmetics circulating in Russia available only for authorities. The aim is to trace each product at every stage of its distribution. Starting from March 1, 2025, operators will be required to register their business on the platform to obtain this QR code.

Subsequently, mandatory labelling of QR Code will be implemented based on HS codes (harmonized System codes), according to the following schedule:

- May 1, 2025: Soaps
- July 1, 2025: Hair products, shaving products, and deodorants
- October 1, 2025: Skin care and makeup products, as well as oral care products.

# Saudi Arabia: Introduction of allergen regulation

Saudi Arabia continues to align with European regulations, particularly regarding ingredient lists. At the end of December, authorities expanded the list of allergens required to be indicated on packaging when over some thresholds, different for rinse-off and leave-on products. The new list of allergens to be labelled when over the threshold concentration is the same as in the EU. Furthermore, the newly published regulation imposes restrictions on methyl salicylate, adding it to the list of restricted substances.

For these 2 requirements, the implementation date is set for December 1, 2026, for market introduction, and December 1, 2028, for the clearance of existing stock.





### Published on Cosmed Regulatory Watch in Q4 2024

#### **EUROPEAN UNION**

- FAQ on Regulation 2024/1781 on ecodesign
- Implementation of Regulation 2023/988 concerning general product safety (GPSR)
- Regulation 2023/1115 against imported deforestation: one-year deadline extension

#### SCCS

- Request for scientific opinion: Methyl Salicylate in cosmetic products intended for children under 3, Tea Tree oil, DHHB (Diethylamino Hydroxybenzoyl Hexyl Benzoate) considering its phthalate content
- Request for evaluation: Butylated Hydroxyanisole (BHA), Benzophenone-2 and Benzophenone-5 within the assessment of potentially endocrinedisrupting substances
- Preliminary opinion: Benzophenone-1, Ethylhexyl Methoxycinnamate regarding potentially endocrine disruptor assessment, HC Red No. 18
- Final opinion: inhalation toxicity of Acetylated Vetiver Oil, new coating for titanium dioxide (nano), Biphenyl-2-ol and Sodium 2-biphenylolate, Hexyl Salicylate considering children's exposure (0-3 years), HC Yellow 16

#### **REACH**

- Substance added to the list of SVHCs: triphenyl phosphate
- Latest updates on ongoing/upcoming restriction intentions
- Publication of the draft Corap plan for 2025–2027

#### CLP

- Publication of ATP 22: CMR 2 classifications for hexyl salicylate, ophenylphenol, and silver
- New CMR classification intentions and adopted classification opinions, including p-cymene

#### **FRANCE**

- Revision in progress for the issuance of GMP certificates
- Publication on environmental claims
- Statement on the risks of hair straightening products containing glyoxylic acid
- Publication on titanium dioxide in cosmetics
- Inspection themes for 2025: GMP, market surveillance, claims, and PIF
- Guidelines to identify and characterize nanomaterials

#### **MAROCO**

- New circular regarding registration
- Provisions relating to cannabis in cosmetics

#### **UNITED ARAB EMIRATES - DUBAI**

- Update of technical guides on fragrances and registration
- Update of the cosmetics analysis sheet
- Clarification regarding Bitrex

#### **EGYPT**

- Extension of the registration deadline
- EDA statement regarding modification requests

#### SAUDI ARABIA

- Guidelines on professional products
- Update of the guideline on product classification
- Customs clearance procedures for bulk and raw materials
- Update of Annex III on restricted substances

#### **UNITED KINGDOM**

- Draft regulation to amend the list of prohibited substances
- Three evaluations have been published: benzophenone-3, octocrylene, and DHA
- Call for data on vitamin A, prostaglandins, alpha and betaarbutin
- ASA decision on an advertisement deemed irresponsible regarding sunrelated risks
- New technical reports on substances under UK-CLP
- OPSS Report on nanomaterials

#### **SWITZERLAND**

- Proposal to amend the ORRChim to ban PFAS and microplastics

#### **TURKEY**

- Draft amendment to the cosmetic regulation
- Implementation of notification fees
- Update of the guides on "free from" claims and on borderline products

#### **EURASIAN ECONOMIC UNION**

- Amendment of the technical regulation TR/TS 005/2011 on packaging safety
- Summary of the main changes from Amendment 3 to the technical regulation on cosmetics
- Russia Regulation implementing mandatory labelling for cosmetics

#### **ISRAEL**

- Draft revision of the cosmetic regulation



### Published on Cosmed Regulatory Watch in Q3 2024

#### **USA**

#### Cosmetics

- Update of the cosmetovigilance factsheet
- Update of the FAQ section of the registration guide
- MOCRA Postponement of deadlines for allergens (January 2025) and GMP (October 2025)
- Publication of the draft testing method for asbestos
- New factsheet on restrictions of heavy metals in packaging (TPCH)
- Final regulation increasing certification fees for colorants
- Publication of EPA activity report on PFAS
- Revision of the Bacteriological Analytical Manual (BAM) on microbiological tests

#### OTC

 End of fee exemption for establishments manufacturing hand sanitizers

#### State regulations

- California Update of the lists of substances to declare
- California "Safer Consumer Products" program, reports on propyland butylparaben and quaternary ammoniums in cosmetics
- California Proposition 65 Final regulation on abbreviated warnings
- Washington Publication of the interim measure regarding lead

#### **CANADA**

- Update of guidelines on declaration form, notification, labelling
- Deadline for the mandatory survey regarding some PFAS

#### **AUSTRALIA**

- Consultation and interim decisions for future amendments to the Poison Standard
- Publication of October 2024 Poison Standard
- Update of the excipient list for Therapeutic Goods

#### **MERCOSUR**

- Draft revision of the lists of prohibited and restricted substances

#### ANDEAN COMMUNITY

- One-year extension for the implementation of new labelling regulation

#### **BRAZIL**

- Regulatory process for personalized cosmetics
- Chemical inventory: official publication of the law, technical regulation pending
- Update of the ingredient list in Portuguese

#### **PANAMA**

- Update of the regulations for cosmetic registrations
- Update of obligations for cosmetovigilance and claims

#### **CHINA**

- Planning for 2024 amendments/additions to the TSSC
- Results of NMPA inspections
- Newly notified cosmetic ingredients, newly registered active ingredient, and canceled ingredients
- Products rejected at customs from August to October 2024

#### **TAIWAN**

Amendment of the guide on the safety assessment of nanomaterialsMinor modifications to the category

#### **INTERNATIONAL**

- Publication of new in-vitro sun protection standards ISO 23675 and ISO 23698



#### COSMETIC REGULATION MONITORING SERVICE

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A unique consultation system allows you to :

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