Overview on regulatory and ingredient-related developments in the EU

2025/12/02

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Status of Regulatory Initiatives under the EU Green Deal – Chemicals Strategy for Sustainability (CSS)

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Five years of stress under the ‘Green-Deal Commission 2019-2024 …

- Flagship Program of the “von der Leyen” Commission
- Probably largest horizontal policy initiative ever at EU level; touching every aspect of EU citizens’ lives;
- Originally driven by the 2030 / 2050 Climate Targets but quickly developing into areas of circularity and ‘zero pollution’.
- Characterised by (almost) unlimited power on the EU regulatory agenda given to the environment department of the EU Commission.
- Triggering a multitude of policy/legislative initiatives;

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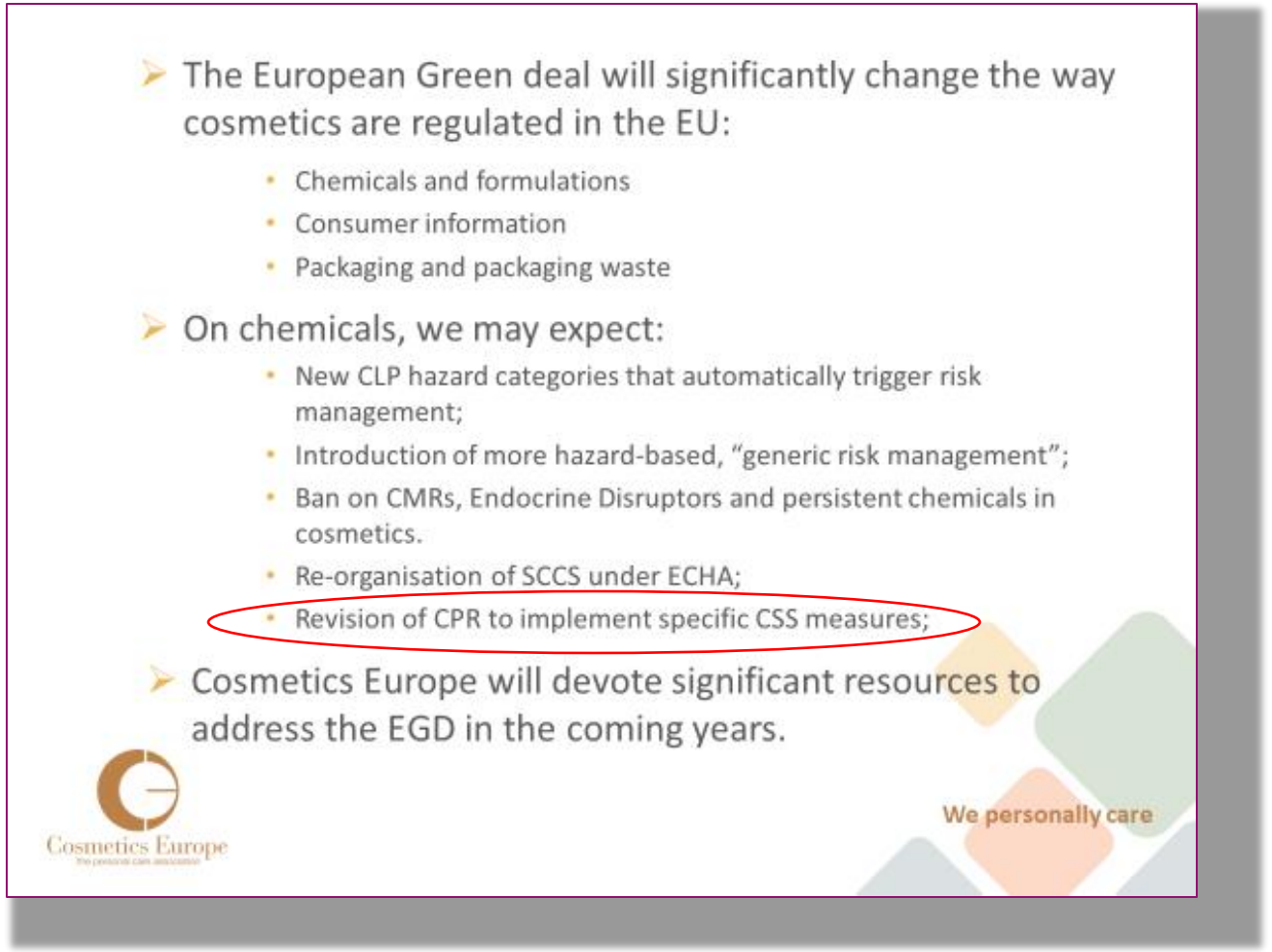
Our assessment three years ago…



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Things were becoming very concrete two years ago…

Legislative initiatives that (will) affect cosmetics

- Revision of CLP Regulation
- Revision of REACH Regulation
- Targeted revision of Cosmetic Products Regulation
- Revision/Recast of Packaging and Packaging Waste Directive
- Regulation on Ecodesign for Sustainable Products (ESPR)
- Directive on Empowering Consumers for the Green Transition
- Green Claims Directive (GCD)
- Urban Wastewater Treatment Directive (UWWTD)
- Regulation of Deforestation-free Products
- Hazardous chemicals – prohibiting production for export of chemicals banned in the European Union

Note: Not all initiatives are equally important from a formulation / safety assessment perspectives, but many have a direct link created through the CLP regulation.

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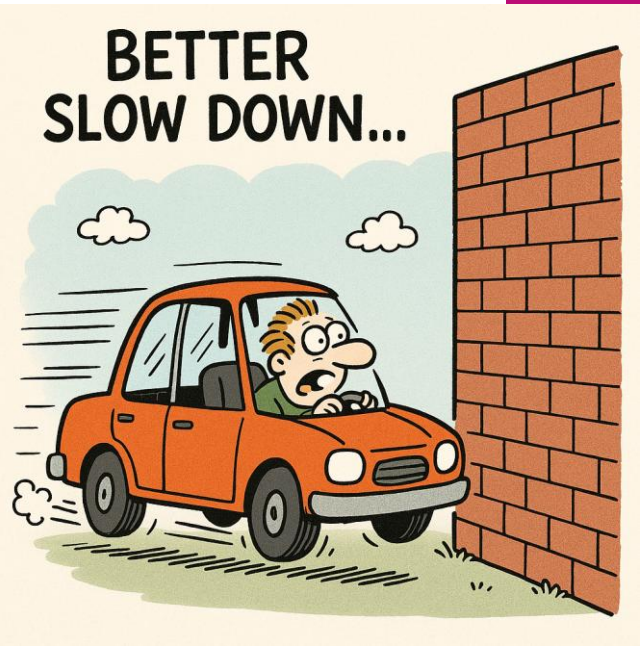
Then …one year of silence ….

After completion of CLP revision and Packaging Waste Regulation, other key initiatives in the area of chemicals legislation were slowed down

- REACH revision
- Targeted Revision of the Cosmetic Products Regulation
- Green Claims Directive

Became ‘unfinished business, handed over to the ‘new Commission and Parliament at the end of 2024.



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The new Commission 2024 – 2029

- Needs to respond to a new geopolitical and economic reality.
- The original visionary/exaggerated Green Deal approach on chemicals is simply not a viable option.
- Development of “A new plan for Europe’s sustainable prosperity and competitiveness”

First pillar

We need a new European Prosperity Plan to:

- ***Make business easier and deepen our Single Market;***
- ***Build a Clean Industrial Deal to decarbonise and bring down energy prices;***
- ***Put research and innovation at the heart of our economy;***
- ***Boost productivity with digital tech diffusion;***
- ***Invest massively in our sustainable competitiveness;***
- ***Tackle the skills and labour gap.***

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Status of Green Deal / CSS implementation

- ✓ Revision of CLP Regulation
  - In force; new hazard classifications start being applied (PBT, PMT, vPvB, vPvM, ED)
  - Problems with implementation timelines for new labelling
- ✓ Revision/Recast of Packaging and Packaging Waste Directive
  - In force; implementing acts being worked on (e.g. standards for recyclability, packaging minimisation)
- ✓ Regulation on Ecodesign for Sustainable Products (ESPR)
  - In force, work ongoing on implementing acts re. destruction of unsold goods and sector-specific ‘sustainability’ criteria / Digital Product Passports
- ✓ Directive on Empowering Consumers for the Green Transition
  - In force, being implemented in national legislations of member states
- ✓ Urban Wastewater Treatment Directive (UWWTD)
  - In force, but fundamental difficulties in implementation

Status of Green Deal / CSS implementation

- Targeted revision of Cosmetic Products Regulation
  - Cancelled and replaced with a evaluation (fitness check)
- Revision of REACH Regulation
  - Significantly delayed, expected to be less radical than originally envisaged
- Green Claims Directive (GCD)
  - Put on ice, future uncertain
- Regulation of Deforestation-free Products
  - Implementation delayed for the second time
- Hazardous chemicals – prohibiting production for export of chemicals banned in the European Union
  - Does not seem to be further pursued

Evaluation of the Cosmetic Product Regulation

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One Year Ago …

Hans Ingels • 1st
Head of Unit - European Commission (Directorate-General for Internal Mar...
2w • Edited •

The Cosmetics Regulation was adopted 15 years ago. Time has come to identify its strengths and its weaknesses, its effectiveness, its efficiency, its EU added value etc. We are launching the evaluation of the Regulation now, and we hope to conclude it during the first half of 2026.

https://lnkd.in/eXhh--Cw

Estefanía Cardamone and 242 others 9 comments · 32 reposts

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What is an “Evaluation” of an EU legislation?

- A normal process for a Regulation in place for 15 years.
- Assessment of a specific EU law for:
  - ✓ effectiveness (whether the law reached its objectives)
  - ✓ efficiency (what are the costs and benefits)
  - ✓ relevance (whether it responds to stakeholders' needs)
  - ✓ coherence (how well it works with other legislations)
  - ✓ EU added value (what are the benefits of acting at EU level)
- The whole legislation, including all its provisions and requirements are in scope of this evaluation.
- Based on the outcome of the evaluation, COM can decide to progress to an amendment/revision of the legislation.

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How is this different from the Targeted Revision ?

- Ultimately, a revision of the Cosmetic Product Regulation **will most likely happen**.
- However, the drivers behind will be radically different from the 'targeted revision' discussed over the past 4 years.
- Targeted revision was **externally imposed** by the Green Deal/CSS and issues / problems identified under the chemicals legislation (REACH, CLP).
- Any revision based on an Evaluation will be **driven from within the CPR**, based on an assessment of what actually works/does not work.

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What are the timelines ?

- ✓ Evaluation started with a Call for Evidence, February/March 2025
- ✓ Public/targeted consultation in May-July 2025
- → Targeted stakeholder consultation in Q4 2025 (now!)
- Results expected by end 2026
- Inception Impact Assessment for CPR revision early 2027
- Impact Assessment and Scrutiny board end 2027
- Commission proposal for revised Regulation early 2028
- Ordinary Legislative Procedure (European Council and Parliament) until early 2029
- Publication of revised Regulation mid 2029

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Which topics will be included in the revision ?

- Difficult to predict. In principle – anything is possible …
- Topics from the “targeted revision" will certainly be brought up again, **unless they have been addressed in the meantime**:
  - Revision of Article 15 (CMR substances) & specific provisions on Endocrine Disruptors;
  - Safety assessment of mixtures/combinations
  - Updated definition of nanomaterials;
  - Management of scientific committee SCCS;
  - Better consumer information through digital means;
  - ‘Lisbonisation’ of the CPR
  - Improved market surveillance
- Other topics have been mentioned: Professional use, Qualification of RP, Expiry date, Sun Protection (2006 Recommendation → Regulation), …

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→ **Note: COM Website shows all comments received during consultations**

Launching, in the meantime, of the “Simplification Omnibuses”

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EU “Simplification” Initiative

- COM objective to reduce regulatory burdens and simplify EU laws → boost competitiveness and safeguard economic, social and environmental goals
- Implementation a series of strategic measures with a target of reducing administrative costs of businesses by > 25% for businesses (35% for SMEs) by 2029
- Systematic identification of opportunities for simplification, consolidation, and improved implementation → meet policy objectives with minimised administrative burden.
- Use of “**Reality checks”:** Technical consultation seeking first-hand, technical feedback from practitioners/businesses on the implementation of EU rules and measures to make them simpler
- Simplification is **prioritised** in annual COM Workplans

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Simplification initiatives planned in the Commission work programme 2025

26 February 2025	First Omnibus package on sustainability
26 February 2025	Second Omnibus on investment simplification
14 May 2025	Third Omnibus package. Common Agricultural Policy simplification
21 May 2025	Fourth Omnibus package. Extension of certain mitigating measures available for SMEs to small mid-cap enterprises and further simplification measures
17 June 2025	Fifth Omnibus package on Defence Readiness
8 July 2025	Sixth Omnibus package on Chemicals
Q4 2025	Simplification of administrative burdens in environmental legislatio
Q4 2025	Military Mobility

Commission Proposal "Omnibus VI – Chemicals" July 2025

- Simplification package for three pieces of Legislation: CLP, Cosmetics, Fertilisers
- Proposed simplification areas for cosmetics:
  - Article 14: Introduction of formal process for adding new positive list materials in the CPR Annexes
  - Article 15: Ban/Derogation of CMR substances
  - Article 16: Nanomaterials notification
  - Article 22: Deletion of annual market surveillance reports by member states
  - Article 33: Deletion of EU glossary of ingredient labelling names

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Simplification Omnibus: Status

- Commission proposal has been published;
- Member States Council is working on its comments/compromise proposal;
- European Parliament needs to appoint rapporteur and shadow rapporteurs;

- In theory, the Simplification Omnibus could be adopted by mid 2026
- In practice, it is not possible to predict – given the unknown level of (dis)agreement in Council and EP.

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Conclusion

- Geopolitics/economic reality have shaped the priorities of the new EU COM;
- Consequently, several key initiatives under the Green Deal/CSS have been postponed / cancelled, such as revision of REACH or Green Claims Directive;
- Also, the targeted revision of the Cosmetic Products Regulation (CPR) has been cancelled;
- CPR revision may still happen – but driven by an evaluation from ‘within’, not driven externally by the Green Deal/CSS.
- COM started a parallel simplification exercise on the CPR – faithful to its ambitious objective to immediately reduce administrative burden of industry;
- Through smart use of SCCS, COM proposal strikes balance of tangible simplification without reducing consumer safety;
- Final outcome will depend on the EU Council and Parliament;
- Stay tuned in 2026 !

Digital Product Passport

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Digital Product Passport

- The Cosmetic Products Regulation (CPR) is no longer the only regulation governing information requirements for cosmetics
- The Ecodesign for Sustainable Products Regulation (ESPR) will introduce the ‘digital product passport’ (DPP) as a:
  - tool for communicating (environmental) **sustainability information** on each product
  - condition for accessing the EU market
- The (upcoming) revision of the CPR is also expected to introduce the DPP as a tool for communicating **digital labelling and compliance information**
- Estimated timing for discussions to start:
  - CPR: end of 2026/Q1 2027
  - ESPR (legislation for the cosmetics sector): 2028

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EU and global context

Globally:

- Numerous countries and regions are discussing / envisaging **e-/digital labelling**, some have legislative proposals (e.g. Vietnam), Brazil and Canada have legislation in place
- The **DPP** is being promoted by the European Commission (e.g. in Canada); Vietnam has included it in draft legislation; discussions are starting in China
- The DPP concept is likely to appeal to regulators; this presents **opportunities** but also **risks**

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Objective and proposed strategic approach

Objective: regulatory compatibility, both in terms of information content and technical backbone

(for the DPP, the latter is linked to 'unique product identification' and standards, and will impact global trade)

Key aspects:

- Information content (on-pack vs digital), beyond current labelling information, potentially including compliance information; **risk**: inclusion of product information file
- Unique product identifier format (move from current barcode to a '2D barcode' by 2027)
- Level of identification (product, i.e. formulation and its packaging; **risk**: batch or item)
- International standards; **risk**: national or regional standards
- Data carriers, e.g. QR codes (1 per product); **risk**: two or more would entail additional text on the label
- Data ownership, confidentiality & maintenance by the Responsible Person; **risk**: centralised product data, authorities issuing the product QR codes

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Packaging and packaging waste regulation

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PPWR:

The PPWR entered into force on **11 February 2025**, with 18month delay of entry into application

Industry is monitoring closely the publication of the secondary legislation on several aspects:

- **Design for Recycling criteria**: European Committee for Standardization (CEN) will soon share their report on DfR criteria for plastics to DG ENV (Commission) so that the latter can start working on a delegated act; CEN is also finalising criteria for glass, aluminium and other materials, but will undergo a consultation review before they are finalised
- **Packaging minimisation**: DG ENV started to work on a list of most common packaging types and formats for which maximum weight and volume limits might be developed by CEN. In the meantime, DG ENV is also drafting a mandate for CEN to update their standard on packaging minimisation (the deadline for DG ENV to send the mandate to CEN is 12 Feb 2027). CEN might already start informal talks on the standard while they wait for the mandate
- **Excessive packaging**: DG ENV will also start working soon on a methodology to calculate the empty space ratio in transport, grouped, and e-commerce packaging. This work will be carried about by the same consultancy working on packaging minimisation
- **Harmonised waste sorting labelling**: Joint Research Centre (JRC) and DG ENV are still in dialogue about this. The JRC is late in delivering the prototype for the harmonised system because of that and we have no clarity on when the prototype will be provided to DG ENV
- **Other packaging labels** (biobased plastics content, Deposit and Return (DRS) systems, reusability, minimum PCR plastic content): DG ENV is developing prototype labels for these. We expect the prototypes to be ready mid-next year at the latest
- **Minimum Post Consumer Recycled (PCR) plastic content**: no updates on the development of the calculation method

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REACH and CPR restrictions

- PFAS
- Microplastics
- Endocrine Disruptors
- CMR
- Other ingredients

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Endocrine Disruptors

2018: Regulatory “Fitness check” concluding that the EU Cosmetics Regulation can, in principle, adequately manage disruptors.

2018,2019: COM established a list of 28 potential ED used in cosmetics and issued a call for data for the 1st set of ingredients in these list.

2020/2021/2022/2023/2024/2025….: Industry safety dossier submissions & SCCS evaluations of substances

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Endocrine Disruptors
Overview Regulatory Process: Priority list A

Finalized
Ongoing
Not Started
Not needed

Name of the substance	Risk Assessment	Risk Management
Benzophenone-3/BP-3/Oxybenzone	Finalized	Finalized
Kojic acid	Finalized	Finalized
4-Methylbenzylidene camphor/4-MBC	Finalized	Finalized
Propylparaben	Finalized	Not needed
Triclosan	Finalized	Finalized
Resorcinol	Finalized	Not needed for ED concerns (changes in Annex will happen due to amendment of a warning statement)
Octocrylene	Finalized	Finalized
Triclocarban/TCC	Finalized	Finalized
Butylated Hydroxytoluene/BHT	Finalized	Finalized/Ongoing*
Benzophenone	Not needed	Finalized
Homosalate	Finalized	Finalized
Benzyl salicylate/IFRA	Finalized	Ongoing
Genistein	Finalized	Finalized
Daidzein	Finalized	Finalized

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*Correction of INCI name in the existing entry: from Butylated Hydroxytoluene to BHT

Endocrine Disruptors
Overview Regulatory Process: Priority list B

Finalized
Ongoing
Not Started
Not needed

Name of the substance	Risk Assessment	Risk Management
Butylparaben	Finalized+Finalized	Not Started
Tert-butylhydroxyanisole/Butylated Hydroxyanisole/BHA	Ongoing	Not Started
Ethylhexyl methoxycinnamate(EHMC)/ Octylmethoxycinnamate (OMC)/Octinoxate	Finalized	Not Started
Benzophenone-1/BP-1	Finalized	Not Started
Benzophenone-2/BP-2	Finalized	Not Started
Benzophenone-4/BP-4	Finalized	Not needed
Benzophenone-5/BP-5	Finalized	Not Started
Methylparaben	Finalized	Not needed
Salicylic acid	Finalized+Finalized	Not Started
Triphenyl phosphate	Finalized	Ongoing
In the original priority list B but excluded from the call for data: Cyclomethicone; Cyclopentasiloxane /Decamethylcyclopentasiloxane /D5; Butylphenyl methylpropianol/BMHCA; Deltamethrin		

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Useful Links to Risk Management Measures of ingredients in ED priority lists

- **2022/1176: Benzophenone-3, Octocrylene -** Regulation - 2022/1176 - EN - EUR-Lex (europa.eu)
- **2022/2195: BHT, Homosalate, Resorcinol** - Regulation - 2022/2195 - EN - EUR-Lex (europa.eu) – Corrigendum 2025/90869 BHT: EUR-Lex - 32022R2195R(02) - EN - EUR-Lex
- **2023/1490: Benzophenone** (CMR Omnibus) - Regulation - 2023/1490 - EN - EUR-Lex (europa.eu)
- **2024/996: Omnibus 1 on Ingredients: 4-MBC, genistein, Daidzein, Kojic Acid, Triclocarban, Triclosan** - Regulation - EU - 2024/996 - EN - EUR-Lex (europa.eu)
- **2026/Omnibus 2 on Ingredients/New regulation voted positive 21/11/25 by MS: Benzyl Salicylate, TriphenylPhosphate:** Will be published in EU Official Journal 1Q 2026

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CMR Substances:

Once a year – EU regulates in the CPR all substances that were classified as CMR in the previous year; default regulation is a ban – exemptions can be granted

- **I Omnibus:** Regulation - 2019/831 - EN - EUR-Lex (europa.eu) Include in the CPR all substances classified as CMR in the past: ie: Formaldehyde
- **II Omnibus:** Regulation - 2019/1966 - EN - EUR-Lex (europa.eu) – Salicylic acid is restriction and others
- **III Omnibus:** Regulation - 2021/850 - EN - EUR-Lex (europa.eu) – Titanium Dioxide (inhalation) restriction and others
- **IV Omnibus:** Regulation - 2021/1902 - EN - EUR-Lex (europa.eu) – Zinc Pyrithione ban and others
- **V Omnibus:**Regulation - 2022/1531 - EN - EUR-Lex (europa.eu) – Methyl Salicylate restriction and others
- **VI Omnibus:** Regulation - 2023/1490 - EN - EUR-Lex (europa.eu) – no ingredient of interest to CE
- **VII Omnibus** Regulation - 2025 /877 - EN - EUR-Lex (eropa.eu) – TPO (Trimethyl benzoyl Diphenyl phosphine Oxide) ban
- **VIII Omnibus** – voted over the summer 2025, but not yet published in OJ– includes restriction of hexyl salicylate, metallic silver, and ortho-phenylphenol (preservative)

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CMR Substances in the pipeline:

- Chemical classification of cosmetic ingredients is accelerating (grouping approach, conservative shortcuts, focus shift from industrial chemicals to substances in consumer products)
- Unprecedented number of CMR classifications in the pipeline for cosmetic ingredients

Ingredient	Comments
Talc	Proposed Classification as CMR
Several Fragrance Ingredients	**p-cymene, heliotropine**, galaxolide, acetophenone, cyclamen aldehyde, bourgeonal, carvone, geraniol and others possible intention to propose CMR classification
Silver chloride	Intention to classify as CMR
Ethanol	Proposed CMR classification triggered by biocide Regulation; possible route specific classification (oral exposure only)
Tea Tree Oil	CMR classification confirmed, derogation process ongoing
~~**Hydrogen Peroxide**~~	CMR classification has been dropped
Sodium Fluoride	Intention to propose CMR classification by France

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European Commission website on CMR substances:

Harmonised classifications of CMR substances and their prohibition under the Cosmetic Products Regulation (CPR)

ATP (Adaptation to Technical Progress)	Amending Regulation to Classification, Labelling and Packaging (CLP)	CPR Omnibus Act	Amending Regulation to CPR	Application date
...	(all previous ATPs)	I	Regulation (EU) 2019/831	12 June 2019
13	Commission Regulation (EU) 2018/1480	II	Regulation (EU) 2019/1966	1 December 2019 and 1 May 202
14	Delegated Regulation (EU) 2020/217	III	Regulation EU 2021/850	9 September 2021
15	Delegated Regulation (EU) 2020/1182	IV	Regulation (EU) 2021/1902	1 March 2022
17	Delegated Regulation (EU) 2021/849	V	Regulation (EU) 2022/1531	17 December 2022
18	Delegated Regulation (EU) 2022/692	VI	Regulation (EU) 2023/1490	1 December 2023
21	Delegated Regulation (EU) 2024/197	VII	Commission Regulation (EU) 2025/877 and TPO in Nail Products – Questions & Answers	1 September 2025
22			Regulation (EU) 202X/XXX	
23				

https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-specific-topics/cmr-substances_en

The upcoming regulatory measures under the CPR, i.e., Omnibus IX on CMR substances, will cover substances newly classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) under the 23rd Adaptation to Technical Progress (ATP 23) to the CLP Regulation. These substances are listed below.

Substances listed in ATP 23 that could be subject to regulatory measures under Article 15 of the Cosmetic Products Regulation (CPR)

	Chemical Name	EC No	CAS No	Hazard Class and Category Code(s)
1	2-ethylhexanoic acid, monoester with propane-1,2-diol	285-503-5	85114-00-7	Repr. 1B
2	α,α'-propylenedinitrilodi-*o*-cresol	202-374-2	94-91-7	Repr. 1B
3	ozone	233-069-2	10028-15-6	Carc. 2 Muta. 2
				Repr. 1B
				Carc. 1B
				Repr. 1B
				Repr. 1B
8	tetrahydrofurfuryl methacrylate	219-529-5	2455-24-5	Repr. 1B

Other ingredients - Risk management latest updates:

- **EU COM's initiative to have an yearly omnibus regulating all ingredients 'recently'' evaluated by the SCCS**

  - **2024/996: Omnibus 1 on Ingredients: 4-MBC, genistein, Daidzein, Kojic Acid, Triclocarban, Triclosan** - Regulation - EU - 2024/996 - EN - EUR-Lex (europa.eu) + Vit.A (Retinol, Retinyl Acetate, Retinyl Palmitate) + Arbutins,
  - **2026/Omnibus 2 on Ingredients/New regulation voted positive 21/11/25 by MS: Benzyl Salicylate, TriphenylPhosphate:** Will be published in EU Official Journal 1Q 2026 + Ammonium Silver Zinc Aluminium Silicate, Aluminium, water-soluble zinc salts, Acetylated Vetiver Oil, Citral, HC Blue No. 18, HC Red No. 18, HC Yellow No. 16, Hydroxypropyl p-phenylenediamine and its dihydrochloride salt, and DHHB ,

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Other ingredients - Risk assessment latest updates:

- **SCCS ongoing evaluations:**
  - **Nano titanium Dioxide:** additional coatings under review
  - **Prostaglandin analogues:** Opinion being finalized
  - **Thiomersal and phenyl mercurates:** Cross sector policy to phase out mercury in all consumer products. Under SCCS review
  - **Salicylates:** Broad range of ingredients, liked by a common CMR 2 metabolite. SCCS mandate under preparation
  - **Synthetic amorphous silica (nanomaterial):** requires an SCCS evaluation
  - **And many more! ie:** CBD, Hair dyes, etc. Check SCCS website

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Other ingredients:

- **impacted under REACH**

- Octocrylene: possible REACH restriction due to environmental concerns
- PFAS & microplastics

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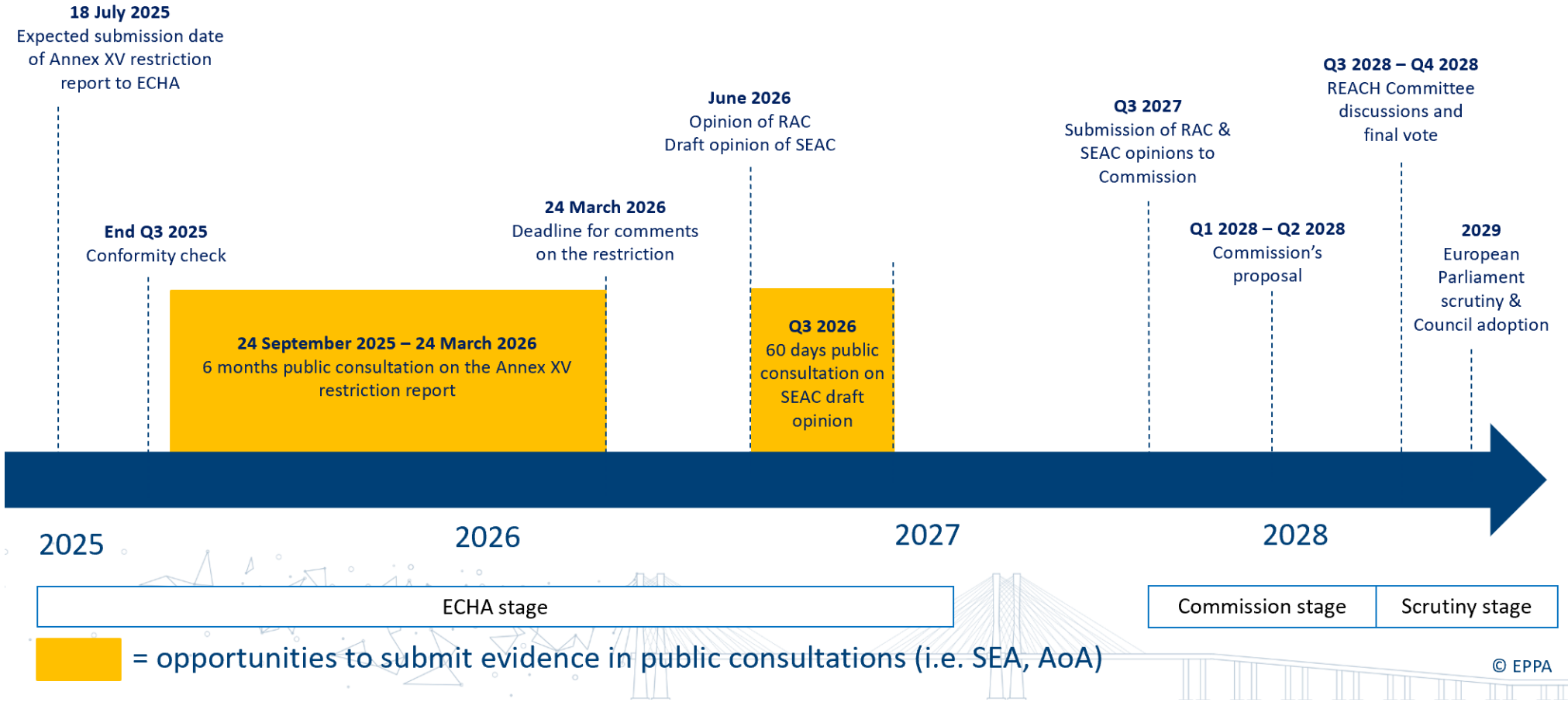
Octocrylene Restriction

- **RO1:** Restriction on placing octocrilene on the market in consumer and professional finished cosmetic products (concentration limit of 0.001% w/w). A two-year transitional period is implemented after the enforcement of the proposed restriction.
- **RO2:** Restriction on placing octocrilene on the market in consumer and professional finished cosmetic products (concentration limit of 0.001% w/w). A five-year transitional period is implemented after the enforcement of the proposed restriction.

Tentative Octocrilene restriction process & timing



PFAS in the EU

- January 2023: ECHA universal restriction proposal for PFAS aims to ban the manufacture, placing on the market, and use of all PFAS unless they are proven essential for society and have no viable alternatives
    - ***Ban on PFAS**: any substance containing at least one carbon atom ($-CF_3$ or $-CF_2$) fully fluorinated (without any H/Cl/Br/I atom). Covers more than 10,000 PFAS substances*
    - *No exemption for cosmetic products*
    - *Prohibition period: 18 months after publication of the text*
    - *Ban on manufacturing, use, or placing on the market*
    - ***Proposed thresholds:***
        - *≤ 25 ppb for each PFAS (excluding polymers) – targeted analyses*
        - *≤ 250 ppb for the sum of PFAS (excluding polymers) – targeted analyses*
        - *≤ 50 ppm of total fluorine in an article (including PFAS polymers) – non-targeted analysis*
- After consultation, some MS authorities noticed that some sectors were missing from the ECHA report on PFAS of January 2023 – background document updated **in August 2025** to include an analysis of these previously omitted areas
    - ECHA report should serve as a basis for Risk-Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) to issue their opinion on the **restriction need and feasibility**
    - ECHA has prepared a draft mapping of PFAS uses to support the upcoming SEAC consultation. Cosmetics are included in this mapping
    - **Consultation on SEAC draft opinion expected in March 2026**
    - internal CE discussion whether the cosmetics sector will provide input for SEAC, especially regarding traces, to ensure appropriate transition timelines

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PFAS in France /!\

- In the meantime, **the French authorities moved ahead and published a decree on PFAs during summer 2025**, and expected to **enter into application by 1/1/2026**
  - Enforcement of the extremely low thresholds identified by ECHA (25ppb), without transitional period for companies to adjust, and **before confirmation from SEAC about the feasibility from the socio-economic standpoint**
  - High concern for the cosmetic industry about the feasibility since the extremely low threshold would conflict with the concept of 'technically achievable traces level' of substances in cosmetics, water contamination, and potential migration from (recycled) plastic packaging's
- The French decree was subject to a TRIS consultation at EU level until 10/11/2025:
  - CE submitted comments arguing that the national legislation conflicts with the European legal framework or creates a barrier to the internal market
    - European Commission found the argumentation borderline and did not agree that the French decree violated EU law (no current EU regulation on PFAS = Member States are allowed to regulate these substances at national level)
    - the French decree is considered outside the CPR scope because discussion on PFAS restriction are from an environmental standpoint (i.e., under REACH)
- **Important point is that once the European Union implements the pan-EU restriction on PFAS, France will be required to repeal its national decree.**

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Microplastics

A reminder of the measures for cosmetics

- Ban on microbeads in rinse off products from Restriction entry into force (EIF)
- Ban on other microplastics in **rinse off** 4 years after EIF
- Except for make-up, lip and nail products, ban on microplastics in leave on cosmetics **6** years after EIF
- Ban on microplastics in make-up lip and nail products **12** years after EIF, provided that after 8 years, such products still containing microplastics should be labelled ‘Contains Microplastics’
- The Restriction was finally published on 17 October 2023;
- This is the date from which the transition period ‘clock’ starts running;

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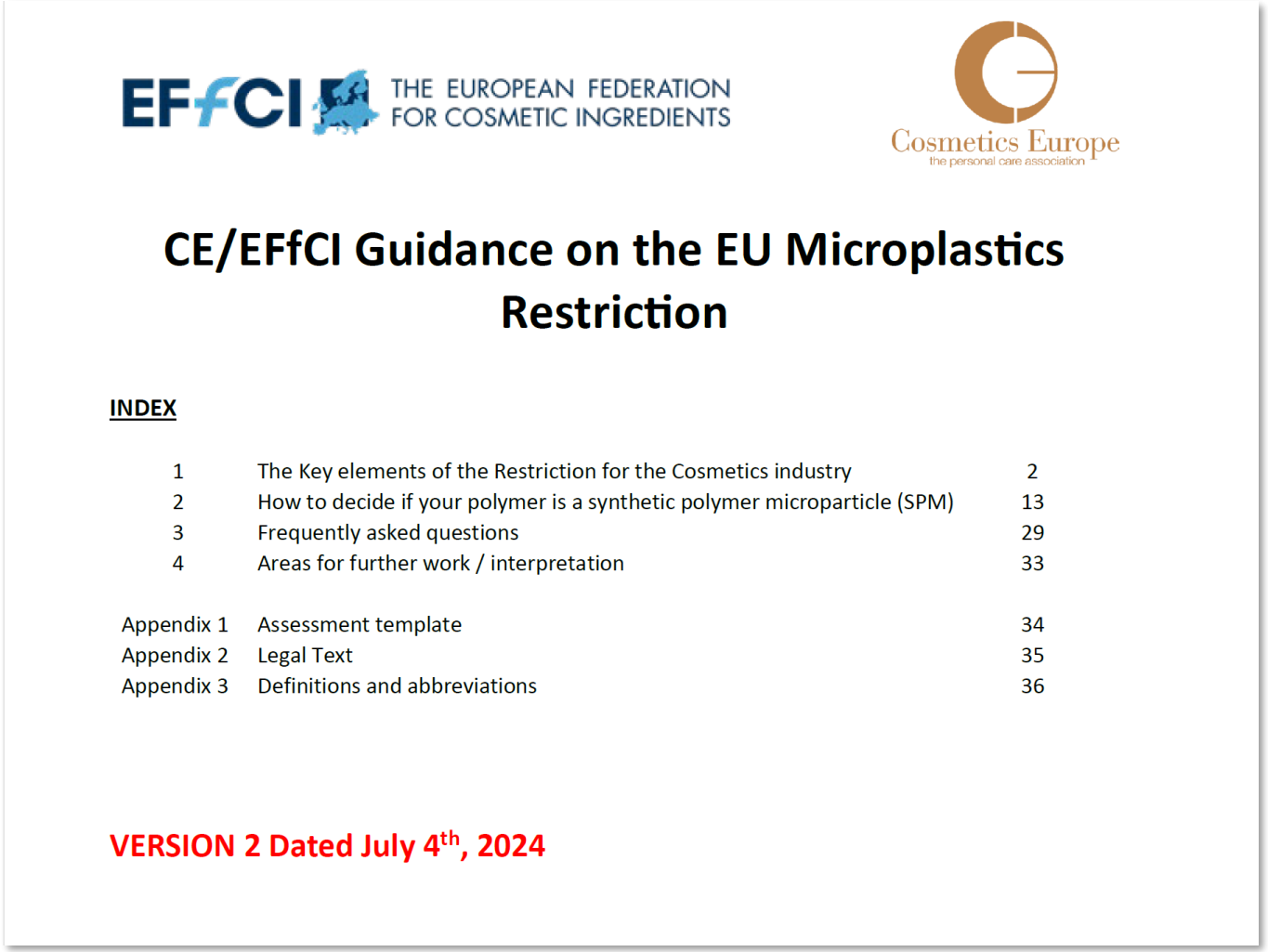
Microplastics

Joint CE/EFfCI Guidance



EFfCI THE EUROPEAN FEDERATION FOR COSMETIC INGREDIENTS

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CE/EFfCI Guidance on the EU Microplastics Restriction

INDEX

VERSION 2 Dated July 4th, 2024

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Microplastics

Commission Guidance

- After a long delay , the Commission published Guidance on the Restriction in April this year

➢ Commission Regulation (EU) 2023/2055 - Restriction of microplastics intentionally added to products - Internal Market, Industry, Entrepreneurship and SMEs

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Microplastics

State of Play (1)

- The first deadline under the Restriction for our industry was October 17 2025 – the use of addition of Instructions for Use and Disposal (IFUD) for some products benefitting from a derogation under the Restriction

- The Derogation relates to the case where microplastics cease to be particles when they are used by consumers (eg film formers)

- Note that the Restriction does not say what the IFUD should be…..

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CE Recommendation on IFUD

- Cosmetics Europe recommends that IFUD should consist of the message '*Do not rinse packaging before disposal*' using the sentence or the following pictogram:

- IFUD do not need to be added to sealed packaging such as aerosols where there is no possibility of the consumer accessing the residue
- The pictogram or the sentence can be on secondary or primary packaging, or the package leaflet
- The pictogram or the sentence should appear in the area where the other 'end of life' information is communicated. It can be supplemented (but not replaced) by digital means
- The European Commission Guidance gives this as an example, but does not mandate it

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State of Play (2)

- By May 2027, manufacturers have to report microplastics emissions for the year 2026
- The relevant emissions are ones from industrial sites and for emissions from derogated products (eg the film formers example, where some particles don't form a film)
- There is no agreed methodology for estimating such emissions
- The objective is to assess the effectiveness of the Restriction, but without a common methodology, it is not clear how this works
- The Reports need to be made to ECHA using a complex software called IUCLID, which many companies are unfamiliar with
- There are already calls for the deadlines to be changed, or for the Reporting requirements to be removed

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Safety assessment of new ingredients

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CPR: Ingredient Defence Process

Safety first!!!

- Article 3: Safety - ...*cosmetic product made available on the market shall be safe for human health...*
- Article 10: Safety Assessment - ... *the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;...*

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The **SCCS Notes of Guidance** for the Testing of Cosmetic Ingredients and their safety evaluation – **12th revision**

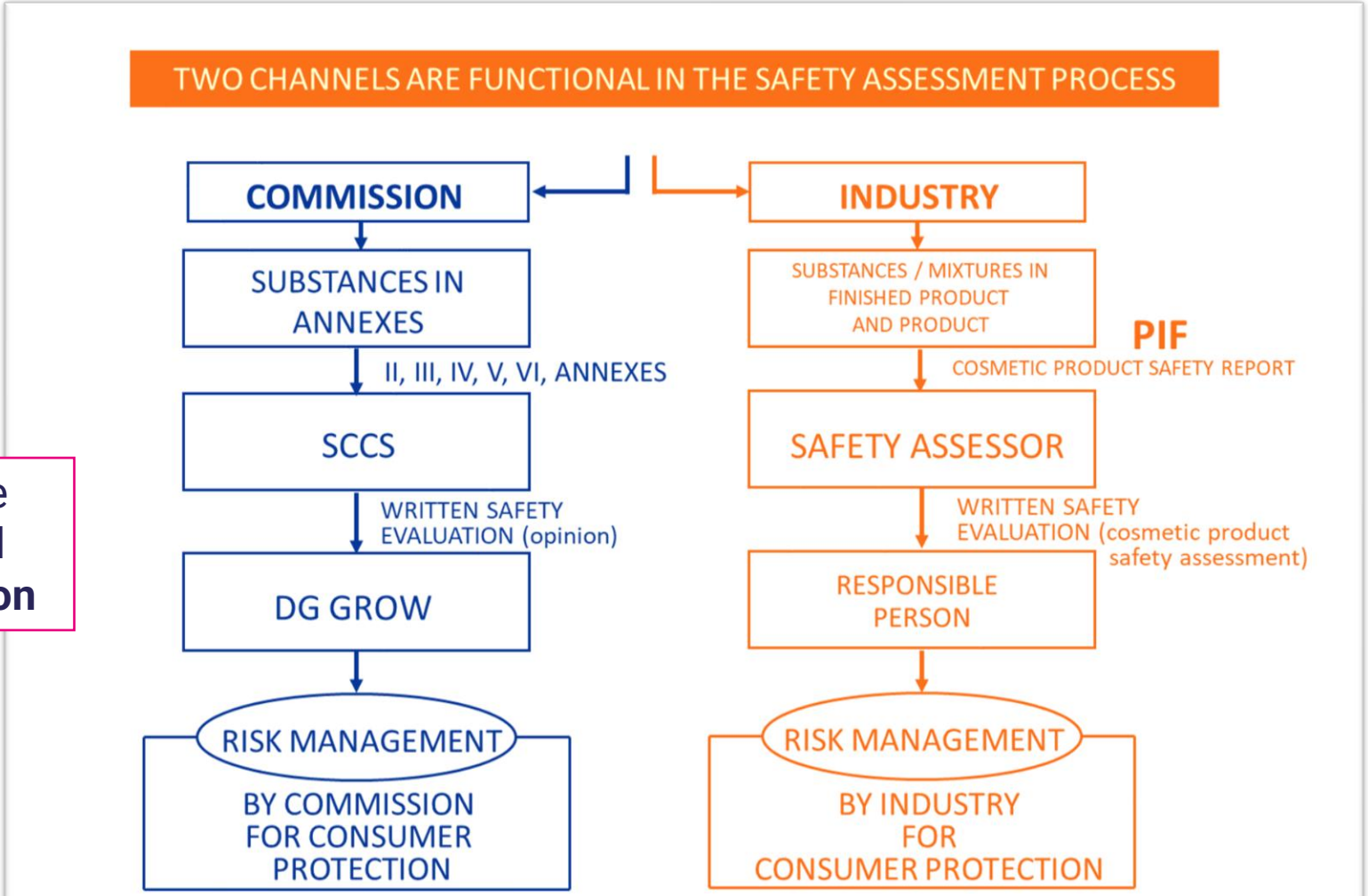

Figure 1: Human health safety evaluation of cosmetic ingredients in the EU.

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When does SCCS get involved?

Chapter IV: Restriction for Certain Substances

- Article 14: Restrictions for substances listed in the Annexes
- Article 15: Substances classified as CMR substances
- Article 16: Nano materials

Chapter VIII: Non-compliance, Safeguard clause

- Article 27: Safeguard Clause

Chapter X: Implementing measures, final provisions

- Article 31: Amendment of the Annexes: potential risk to human health, arising from the use of substances in cosmetic products

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What about new ingredients?

- Ingredient Function
  - Annexes CPR: SCCS opinion is needed + Follow up risk management
  - Others: Safety Assessor safety assessment
- Animal Testing Ban
- Free From Claims

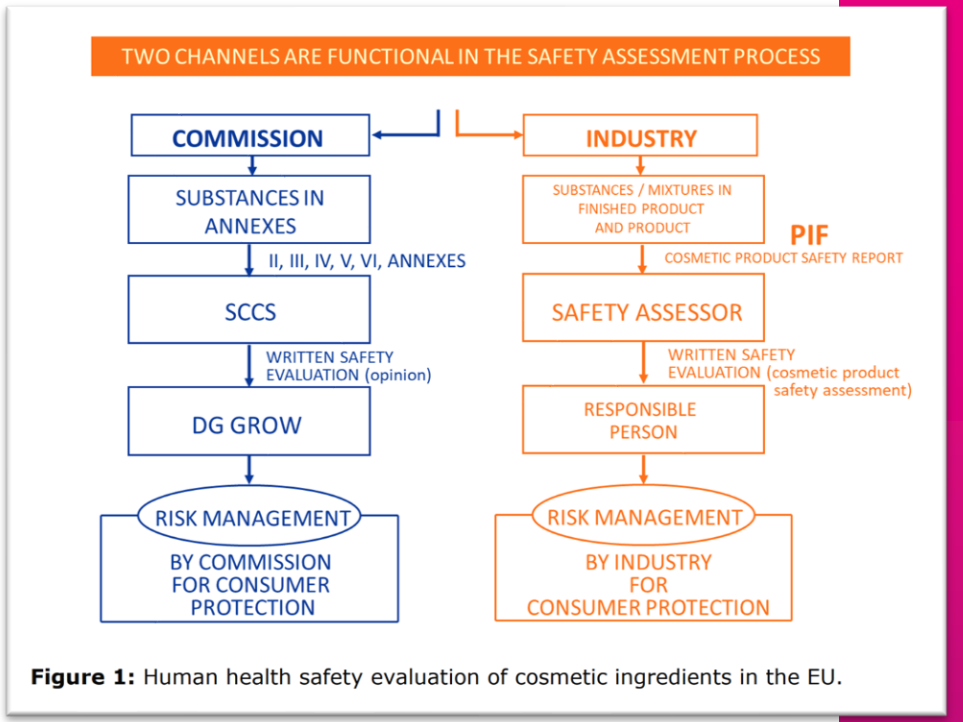

Figure 1: Human health safety evaluation of cosmetic ingredients in the EU.

For new and existing ingredients

- Difficulty in predicting future chemical scrutiny
  - A **must**: Regulatory monitoring
  - Some other ideas:
    - ✓ Vulnerabilities in Safety information available
    - ✓ Data Rich versus Data Poor Chemicals
    - ✓ Impact of REACH tonnage band for availability of toxicological and ecotoxicological information – evolution over time

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What about animal testing?

In the European Union, **animal testing is prohibited** for:

- Finished cosmetic products → Since September 2004
- Ingredients/ combination of ingredients → Since March 2009
- Products containing ingredients tested outside the EU → Since March 2013

How to assess safety then?

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New Approach Methodologies (NAMs)

"Any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment, and avoid the use of animals, and may include in silico, in chemico and in vitro approaches"

- **Mechanistic approach**
- **Human- relevant exposure**
- **Combination of NAMs and new technology** with **historical animal data**, when available- **Weight of Evidence (WoE)**
- One possibility for integrating NAMs and these new types of info into safety decision making is the **Next Generation Risk Assessment (NGRA)**, a **human- relevant**, **exposure-led** and **hypothesis- driven approach** that has the potential **to support animal-free safety decision-making**
- The **SCCS NoG** describe safety assessment of cosmetic ingredients and the different non-animal methods that can be used in safety assessment

Ab initio chemical safety assessment: A workflow based on exposure considerations and non-animal methods

Elisabet Berggren [1], Andrew White [2], Gladys Ouedraogo [3], Alicia Paini [1], Andrea-Nicole Richarz [1], Frederic Y Bois [4], Thomas Exner [5], Sofia Leite [6], Leo A van Grunsven [6], Andrew Worth [1], Catherine Mahony [7]

Paving the way for application of next generation risk assessment to safety decision-making for cosmetic ingredients

M.P. Dent[a,*], E. Vaillancourt[b], R.S. Thomas[c], P.L. Carmichael[a], G. Ouedraogo[d], H. Kojima[e], J. Barroso[f], J. Ansell[g], T.S. Barton-Maclaren[b], S.H. Bennekou[h], K. Boekelheide[i], J. Ezendam[j], J. Field[b], S. Fitzpatrick[k], M. Hatao[l], R. Kreiling[m], M. Lorencini[n,1], C. Mahony[o], B. Montemayor[p], R. Mazaro-Costa[q], J. Oliveira[r], V. Rogiers[s], D. Smegal[k], R. Taalman[t], Y. Tokura[u], R. Verma[k], C. Willett[v], C. Yang[w]

Principles underpinning the use of new methodologies in the risk assessment of cosmetic ingredients

Matthew Dent[a,*], Renata Teixeira Amaral[b], Pedro Amores Da Silva[b], Jay Ansell[c], Fanny Boisleve[d], Masato Hatao[e], Akihiko Hirose[f], Yutaka Kasai[g], Petra Kern[h], Reinhard Kreiling[i], Stanley Milstein[j], Beta Montemayor[k], Julcemara Oliveira[l], Andrea Richarz[m], Rob Taalman[n], Eric Vaillancourt[o], Rajeshwar Verma[j], Nashira Vieira O'Reilly Cabral Posada[l], Craig Weiss[p], Hajime Kojima[f]

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ICCR
International Cooperation on Cosmetics Regulation

Product claims and labelling

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Cosmetic claims: compliance check

EU cosmetic regulation requirements:

- Claims compatible with the cosmetic definition (i.e., primary cosmetic function that it is not a drug)
- Principles and boundaries for claims, **but** does not prescribe/ban specific wording
- Claims are truthful and supported by evidence
- Scientific best practice for claim substantiation, **but** does not prescribe specific efficacy test methods
- Entity placing the product on the market responsible for compliance
- National authorities to check compliance of claims/substantiation via in-market control

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Product labelling: claims

EU six common criteria for claim

Commission Regulation (EU) No 655/2013

- Legal compliance
- Truthfulness
- Evidential support
- Honesty
- Fairness
- Informed decision-making

EU technical document on cosmetic claims

Version of 3 July 2017

To support the Responsible Person and the authorities to provide a proper substantiation of cosmetic claims

EU '*borderline manual*'

v.5.5 of June 2025 by the EU sub-working group on borderline products

To assist the Responsible Person and relevant authorities in determining whether claims pertain to cosmetics or drugs.

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“Hypoallergenic”

EU technical document on cosmetic claims

ANNEX IV - Hypoallergenic claim

- May only be used if the product is **designed to minimise allergenic potential**
- Based on scientifically robust and statistically **reliable data** confirming a very low allergenic potential of the product (e.g., post-marketing surveillance), updated continuously
- Formulation Rules: **no known allergens or precursors** (=non detectable), including:
  - SCCS-identified sensitizers or other official risk assessments
  - CLP Regulation Category 1 (1A/1B) skin sensitizers
  - Ingredients flagged by company complaints or scientific literature
  - Substances lacking sensitisation data
- /!\ The use of the claim "hypoallergenic" **does not guarantee a complete absence of risk of an allergic reaction** and the product should not give the impression that it does
- Additional Guidance:
  - Refer to SCCS Memorandum on human data (SCCS/1567/15) about the use of human data in risk assessment of skin sensitisation
  - Ensure consumers understand the claim; provide clarification if needed

“Natural and Organic”

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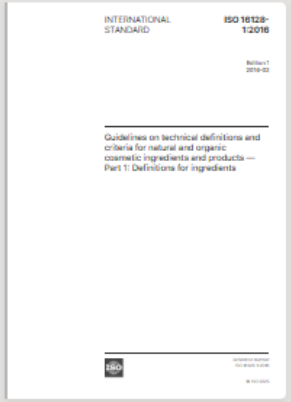

Read sample

ISO 16128-1:2016

Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products

Part 1: Definitions for ingredients

Published (Edition 1, 2016)

Abstract

ISO 16128-1:2016 provides guidelines on definitions for natural and organic cosmetic ingredients.

In addition to natural and organic ingredients, other ingredient categories which may be necessary for natural and organic product development are defined with associated restrictions.

ISO 16128 does not address product communication (e.g. claims and labelling), human safety, environmental safety and socio-economic considerations (e.g. fair trade), and the characteristics of packaging materials or regulatory requirements applicable for cosmetics.

“Natural and Organic”

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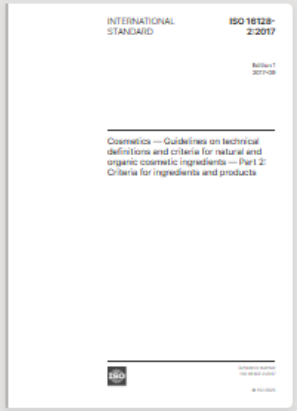

Read sample

ISO 16128-2:2017

Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients

Part 2: Criteria for ingredients and products

Published (Edition 1, 2017)

Abstract

ISO 16128-2:2017 describes approaches to calculate natural, natural origin, organic and organic origin indexes that apply to the ingredient categories defined in ISO 16128-1. This document also offers a framework to determine the natural, natural origin, organic and organic origin content of products based on the ingredient characterization.

Neither ISO 16128-1 nor this document addresses product communication (e.g. claims and labelling), human safety, environmental safety, socio-economic considerations (e.g. fair trade), characteristics of packaging materials or regulatory requirements applicable for cosmetics.

ISO 16128-2:2017 builds on and enhances ISO 16128-1. It is intended to be used in conjunction with ISO 16128-1.

“Natural and Organic”

- Whilst there are existing guidance/standard on how to measure the % of natural and/or organic origin of a cosmetic product based on its raw materials, **there is no harmonized/legal requirements prescribing how to claim natural and organic content in the EU**

➢ the 6 common criteria for cosmetic claims apply:
  - Legal compliance
  - **Truthfulness**
  - **Evidential support**
  - **Honesty**
  - Fairness
  - Informed decision-making

➢ Possibility to defer on external certification scheme (COSMOS, NATRUE…) to benefit from well-known natural and organic criteria in cosmetics

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