Congrès Enjeux Réglementaires Parfums & Cosmétiques

19-20 November 2025

'Shaping the future of Cosmetics Regulation: Insights from the CPR Evaluation and beyond'

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1. **Regulatory updates** – (a) *where are we and (b) what's in the pipeline?*

2. The **Evaluation** of the Cosmetic Products Regulation

3. COM(2025)531 – Proposal for the **simplification** of certain requirements and procedures for chemical products (*Omnibus on Simplification*)

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1. Regulatory Updates (a) (1/3)

- The **Omnibus VII on CMRs** is based on ATP 21 and the Delegated Regulation 2024/197 applicable from **1st September 2025** (*TPO*).

- The **Omnibus VIII on CMRs** is based on ATP 22 and the Delegated Regulation 2024/2564 applicable from **1st May 2026** (*Hexyl Salicylate, Silver, OPP/OPP-Na*).

- Preparation of **Omnibus IX on CMRs** based on ATP 23 (*no contested ingredients*).

***CMR**: carcinogenic, mutagenic, reprotoxic.*
***ATP**: Adaptation to Technical Progress.*

1. Regulatory Updates (a) (2/3)

- The **Omnibus 2 on cosmetic ingredients.**
  - Ø Draft Regulation shared with Cosmetic Products Working Group (CPWG)
  - Ø The submission to the World Trade Organisation (WTO) in the context of Technical Barriers to Trade (TBT) is completed
  - Ø Possible vote during the Standing Committee meeting in November 2025

Ingredients covered:

- Triphenyl Phosphate (TPP)
- Silver Zinc Zeolite
- Aluminium containing ingredients
- Water-soluble zinc salts
- Acetylated vetiver oil (AVO)
- Citral (Geranial/Neral)
- Benzyl Salicylate
- The hair dyes:
  - ü HC Blue 18
  - ü Hydroxypropyl p-phenylenediamine & its H_2Cl_2 salt
  - ü HC Yellow16
  - ü HC Red 18
- The UV filter DHHB (DnHexP, 10ppm)

1. Regulatory Updates (a) (3/3)

- The updated version of the **Glossary** of common ingredient names is published in the Official Journal (OJ) covering more than 30,000 names for labelling purposes.

- **Corrigenda** under preparation:
  - Commission Regulation (EU) 2023/1545 (*correction + addition of missing INCI names*)
  - Commission Regulation (EU) 2022/2195 (*correction of INCI - Butylated Hydroxytoluene-BHT*)

Regulatory Updates (b) – *Endocrine disruptors (1/3)*

Benzophenone-3 þ	4-MBC þ	Kojic Acid þ	Benzophenone-4 þ
Benzophenone þ !!	Triclocarban þ	Propylparaben þ	Triphenyl phosphate þ
BHT þ	Triclosan þ	Butylparaben þ	Benzophenone-5 þ
Resorcinol þ	Benzyl Salicylate þ	Methylparaben þ	Benzophenone-2 þ
Octocrylene þ	Genistein þ	Salicylic acid þ	Ethylhexyl methoxycinnamate (EHMC/OMC) þ
Homosalate þ	Daidzein þ	Benzophenone-1 þ	BHA (Butylated Hydroxyanisole) 6

þ Completed þ !! Treated via Omnibus VI on CMRs 6 Preliminary Opinion

Regulatory Updates (b) – *other ingredients (2/3)*

Aluminium þ	O-Phenylphenol, Na/K salts ***(CMR** derogation request)* þ	Methyl Salicylate – children's exposure þ
TiO_2 new assessment 6	HC Yellow 16 þ	Cannabidiol (CBD) 6
Hydroxyl propyl p-phenylene diamine and its salt (A165) þ	HC Red 18 þ	Tea tree oil (TTO) (CMR derogation) %
Citral þ	Prostaglandins %	Mercury compounds 6
Vetiver Oil þ	Diethylamino hydroxybenzoyl hexyl benzoate (DHHB) – DnHexP þ	Basic Brown 16/Basic Blue 99 6
Hexyl Salicylate ***(CMR** derogation request)* þ	Salicylic Acid – children's exposure þ	Silica (nano) 6
Silver (elemental) ***(CMR** derogation request)* þ	Butyl Paraben – children's exposure þ	Hydroxyapatite (nano) þ

þ Completed

6 Ongoing SCCS assessment

6 Preliminary Opinion

% Under finalisation

***CMR**: Carcinogenic, mutagenic, reprotoxic*

Regulatory Updates (b) – *Ongoing work (3/3)*

TiO_2 new assessment	6	Prostaglandins	%
Silica (nano)	6	BHA (Butylated Hydroxyanisole)	6
Heliotropine *(**CMR** derogation request)*	6	Mercury compounds (Thimerosal, Phenylmercuric salts)	6
TTO *(**CMR** derogation request)*	%	Cannabidiol (CBD)	6
Acetophenone *(**CMR** derogation request)*	6	Salicylic Esters	💬
Basic Brown 16	6	Cresyl Methoxycinnamate (MMPC) (new UV-filter)	6
Basic Blue 99	6		

6 Ongoing SCCS assessment

💬 Discussions

6 Preliminary Opinion

% Under finalisation

Possible Commission measures following the SCCS conclusions

European Commission

2. The **Evaluation** of the Cosmetic Products Regulation (CPR) (1/7)

***Why** evaluating the CPR?*

1. CPR adopted in 2009 and applicable since July 2013 – no review clause but according to the Better Regulation Guidance, an EU act should be revised after 7 – 10 years.

2. Work on the ***targeted revision*** of the CPR showed that apart from areas identified in Chemicals Strategy for Sustainability (CSS), there are **other areas needing revisiting**.

3. Changes in the ***broader regulatory context*** advocate for a comprehensive and not piece meal approach.

European Commission

2. The **Evaluation** of the CPR (2/7) – **Objectives**

The **General Objectives** of the CPR:

1. to maintain a high level of consumer **safety** (*i.e., the high standard of safety must not be lowered*)

2. to smoothen the **functioning of the single market** (*cosmetics being harmonised products, which can move freely in the EU if compliant with the CPR*)

2. The **Evaluation** of the CPR (3/7) – **Criteria**

Scope of the evaluation of the CPR – 5 Criteria

Effectiveness: To what extent has the Regulation contributed to protecting human health, while enabling cosmetic products to circulate freely in the single market? To what extent have its specific objectives been achieved?

Efficiency: What are the main benefits (including cost savings) and costs of the implementation of the Regulation?

Relevance: Is the Regulation able to meet current needs, or is it outdated, including in the context of the *green* and *digital transitions* and the *competitiveness* of the EU industry? Are the current rules sufficient to ensure the safety of the products for both *consumers* and *professionals*, including in view of the development of *online sales* or “bulk sales”, as well as expanding knowledge on safety of substances?

European Commission

2. The **Evaluation** of the CPR (4/7) – Criteria

*Scope of the evaluation of the CPR – **5 Criteria***

Coherence (consistency): Is the Regulation *internally consistent*, and does it *align with other chemicals legislation*, such as CLP, REACH, Detergents, Biocides, Medical Devices and Pharmaceuticals? Is it coherent with other relevant legislation, e.g., the EU consumer protection rules?

EU 'added value': Could the objectives of the Regulation have been addressed at national level only or is EU-level legislation on cosmetics necessary?

***CLP**: classification, labelling and packaging of substances and mixtures.*
***REACH**: Registration, Evaluation, Authorisation and Restriction of Chemicals.*

European Commission

2. The **Evaluation** of the CPR (5/7) – Consultation

Call for Evidence:
21 February - 21 March 2025

- The call for evidence for this initiative will be open for **public feedback;**
- Hosted on the Commission's **Have Your Say** website;
- For at least **4 weeks;**
- In **all** EU languages**;**
- Gather preliminary **reactions** from stakeholders on the main **aspects of the initiative**.

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Public Consultation:
05 May - 28 July 2025

- The open public consultation for this initiative will be hosted on the Commission's **Have Your Say** website;
- For at least **12 weeks;**
- In **all** EU languages**;**
- Gather **data/views** from various stakeholders based on the evaluation criteria;
- **Factual summary** published within **8 weeks** from closure.

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Targeted Consultation:
October 2025

- The targeted consultation for this initiative will be performed by the consultant;
- Gather **data/views** from the most relevant categories of stakeholders;
- It will include **questionnaires, surveys** and **interviews**;
- Results to be included in the **draft final report** and presented in a dedicated **workshop**.

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2. The **Evaluation** of the CPR (6/7) – Stakeholders

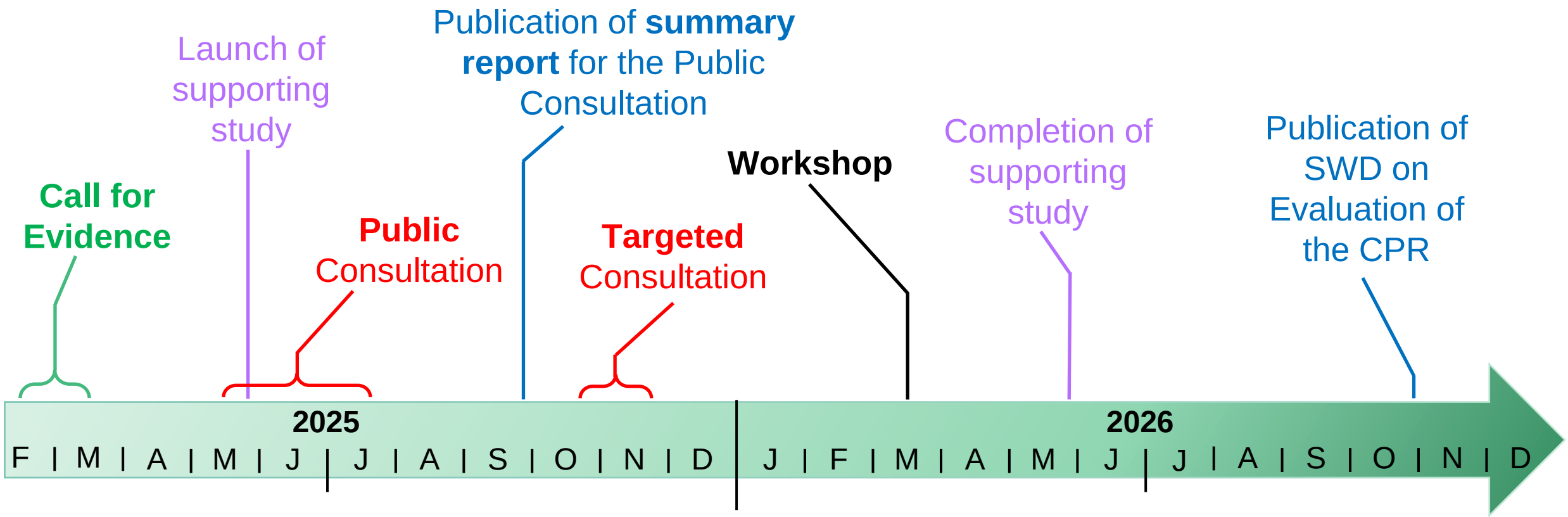
Stakeholder mapping:

- **Public administrations**, national and regional authorities (such as market surveillance authorities; law enforcement authorities/agencies);
- **Industry associations** (including manufacturers/suppliers/importers of ingredients and manufacturers/suppliers/importers and professional users of cosmetic products) at EU, national and/or international level;
- **Businesses**, including multinational enterprises as well as large, medium, and small companies (focus on SMEs);
- **Academia**/think tanks, research and technology organisations/institutes;
- **Individuals/consumers;**
- **Non-Governmental Organisations** and civil society including consumer and environmental NGOs (at EU, national and/or international level);

***SMEs**: Small and medium-sized enterprises.*
***NGOs**: Non-governmental organizations.*

2. The **Evaluation** of the CPR (7/7) – Timelines

***Indicative** timeline of the evaluation:*



***SWD**: Staff Working Document.*
***CPR**: Cosmetic Product Regulation.*

3. Omnibus on Chemicals Simplification (1/8)

*Communication on **implementation** and **simplification** (a simpler and faster Europe):*

- Simplification as a key political priority aimed at **making business operations easier** and **faster** in the EU.
- Systematic reviews of existing rules to **identify opportunities** for **simplification.**
- Goal: to deliver **fast** and **visible improvements** for people and businesses, contributing to a more prosperous and resilient EU.
- The “reality check” workshop is a **new consultation tool** with the stakeholders.
- This workshop aimed to harness **feedback from stakeholders in the cosmetics area** (especially SMEs).

3. Chemicals Simplification (2/8) – Article 14

Current situation - issues identified:

Ø **Lack of a clear procedure** was indicated as a potential obstacle to submitting a dossier and hindering sector's innovation.

Commission Proposal:

Ø New Article 14, laying down a comprehensive procedure

- clarifying that this procedure is initiated following a *request from the industry*.
- all *actors* (industry, COM, SCCS, etc.) and their roles, as well as *timelines* before amending Annexes III – VI.

3. Chemicals Simplification (3/8) – Article 15

Lack of legal clarity and predictability:

- The **same application date** of Omnibus Act on CMR substances and Delegated act under CLP for the harmonised classification creates issues for downstream users.
- The **timeline to request derogation** is not laid down in the CPR, but informally agreed between competent authorities and the industry as part of the CMR Guidelines.

- Lack of **transitional periods** for substances banned/restricted from use in cosmetics due to their CMR classification – *no time to reformulate, relabel, withdraw from the market of not compliant products.*

European Commission

3. Chemicals Simplification (4/8) – Article 15

Issues with the derogation criteria:

- *Application for **particular use** of a product category with known exposure is already part of the dossier for the SCCS, thus can be deleted.*

- *Modern risk assessments already consider bioavailability and systemic exposure.The **food safety criterion** creates redundant and impractical barriers especially for the ingredients not found/used in food. Furthermore, unlike food, cosmetics are not ingested, and their exposure routes differ significantly.*

- The impact of the harmonised classification as a CMR substance of a **constituent** on the approach to a **Natural Complex Substance (NCS)** is not clear. The consequences for the cosmetic business of one interpretation can be significant.
- Substances are classified as CMR category 1A or 1B due to the **oral and inhalation exposure**. Substances are banned from cosmetic products though they are safe for human health if used on the skin (dermal exposure).

3. Chemicals Simplification (5/8) – Article 15

Commission Proposal:

Procedure

- Define the **period for derogation request**: e.g. 3 months from the date of entry into force of the ATP.
- Define **transitional periods**: e.g. For new products and for products already on the market, counted from the entry into application of CPR measure.

Simplified derogation criteria

- Application for particular use of a product category with known exposure could be deleted from the list of criteria.
- Compliance with food safety requirements can be deleted from the list of criteria.

New provisions

- Clarification that the CMR harmonised classification of a **constituent of a NCS** does not lead to the ban on the use of this NCS in cosmetics.
- Clarification that CMR harmonised classification due to **other exposure than dermal does not trigger the ban** under article 15 of the CPR.

3. Chemicals Simplification (6/8) – Article 33

Current situation - two sources for cosmetic ingredient names:

- A **Glossary** adopted by the COM (COM Decision) and published in the Official Journal, updated approximately every 2-3 years.
- **CosIng** – electronic database with regular updates (no legal value).

Commission Proposal:

- Instead of glossary – the CPR would refer to *internationally recognised nomenclature*.
- CosIng could continue to exist and provide easy access to the information on *substances and some information on ingredients.*

***CosIng**: Cosmetic Ingredients database.*

3. Chemicals Simplification (7/8) – Articles 16 & 22: Reducing **notification** and **reporting** obligations

Commission Proposal:

Deletion of **prenotification** requirements for products containing nanomaterials (Article 16).

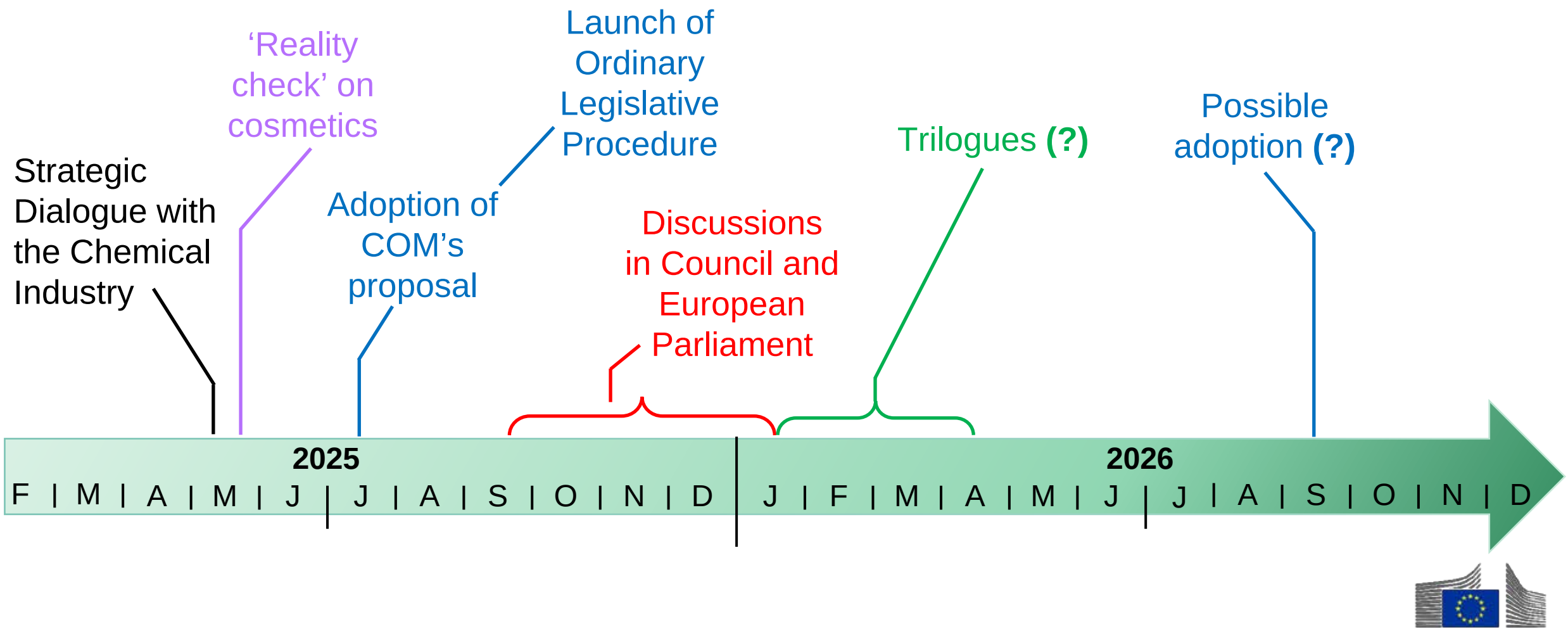
Notification under Article 13 would be sufficient to ensure safety of cosmetic products.

Deletion of market surveillance **reporting** obligations (Article 22, fourth subparagraph).

The relevant information can be extracted via the ICSMS.

3. Chemicals Simplification (8/8) – Timelines

***Indicative** timeline for the simplification proposal:*



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Thank you !

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